

NIH POLICY MANUAL

2300-735-4 OUTSIDE WORK AND RELATED ACTIVITIES WITH OUTSIDE ORGANIZATIONS

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1. **Explanation of Material Transmitted:** This chapter is being revised to reflect changes and revisions resulting from changes in the government-wide standards of conduct and/or changes in NIH policy.

2. **Filing Instructions:**

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PLEASE NOTE:

This chapter has undergone **major revisions** based on Government-wide changes in the standards of conduct, comments from the Office of Government Ethics following their audit of the NIH Ethics Program, and elimination of the Honoraria Ban. It should be read in its entirety and employees informed of the availability of the revised chapter.

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- A. **PURPOSE:** This chapter states the policies, guidelines, and procedures which govern the activities of NIH staff with outside organizations, including outside work, official duty activities, and the acceptance of awards and honorary degrees from outside organizations.

Comprehensive regulations on outside work applying to all Federal employees are contained in the Office of Government Ethics (OGE) Standards of Ethical Conduct for Employees of the Executive Branch (5 C.F.R. Part 2635). This NIH Manual chapter interprets and is intended to be used in conjunction with the OGE Standards of Ethical Conduct for Employees of the Executive Branch and the Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services (DHHS).

- B. **POLICY:** NIH regards the participation of its employees in professional associations, societies, executive boards and committees of non-Federal organizations as vital to maintaining an intellectually stimulating and productive work environment. NIH also views activities with outside organizations as appropriate aspects of professional development for employees. While NIH encourages participation in outside organizations, such participation can raise ethical concerns. Employees engaging in activities with outside organizations are responsible for complying with the OGE Standards and the DHHS Supplement; avoiding conflicts of interest; and refraining from participation in any activities that conflict or appear to conflict with the policies, programs or operations of the NIH, DHHS, or the Executive Branch. Because failure to observe these requirements may be cause for disciplinary or legal action, NIH provides extensive guidance and assistance to employees so that their participation in outside organizations will be positive and rewarding experiences free of any complications or problems.
- C. **COVERAGE:** This chapter applies to all Civil Service and Commissioned Corps employees, including employees in the General Schedule, Federal Wage System, Senior Executive/Scientific Service, Senior Level, and the Senior Biomedical Research Service. Coverage also extends to employees appointed to Title 42 positions such as service fellows, Visiting Associates and Scientists, and Special Experts and Consultants. It also applies to persons working at NIH under Intergovernmental Personnel Act assignments.

This chapter also applies to persons who are not NIH employees, i.e., National Research Council Research Associates, Guest Researchers (including Scientist Emeriti) and Special Volunteers. Intramural Research Training Awardees and National Research Service Awardees at the NIH, although not employees, are required by training agreements to adhere to the standards and provisions set forth in this instruction.

This chapter does not apply to Visiting Program staff (all visa holders) who may be prohibited from engaging in outside activities by visa restrictions, nor to Special Government Employees who work 130 days or less during a service year. Individuals not covered by this Chapter may contact their Deputy Ethics Counselor (DEC) or Ethics Coordinator for other ethics information.

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D. RESPONSIBILITIES:

1. **Director, NIH** is responsible for: a) establishing NIH policies and procedures to implement the Government-wide standards of conduct and DHHS supplemental standards relating to activities with outside organizations; and b) making program or policy exceptions when justified by special circumstances.
2. **ICD Deputy Ethics Counselors** are responsible for: a) coordinating and managing Institute, Center and Division (ICD) ethics programs; b) providing advice to managers and employees regarding the application of the standards of conduct, and policies on activities with outside organizations; c) reviewing requests for activities with outside organizations for conformance with regulations and policies and approving or disapproving requests as needed; d) approving waivers and written recusals, and e) assuring the maintenance of all records associated with ICD employee activities with outside organizations. The review and approval authority may be delegated to other ICD managers consistent with the NIH delegations of personnel authorities.
3. **NIH Office of Human Resources Management (OHRM)** is responsible for: a) providing assistance to Deputy Ethics Counselors, ICD Ethics Coordinators, and other managers and supervisors on all aspects of the NIH Ethics Program including activities with outside organizations; b) conducting post audit reviews consistent with NIH Management Control guidelines; c) advising the Director, NIH, and other top management officials of new developments, trends or practices associated with the participation of NIH employees in outside organizations; and d) providing assistance on informal or formal training for ICD officials as needed.
4. **DHHS Office of the General Counsel, Ethics Division (OGC/ED)** is responsible for maintaining an office at the NIH for the purposes of: a) administering and implementing the Ethics Program at NIH; b) functioning as the NIH liaison to the Office of Government Ethics; and c) providing advice and assistance in developing policies compatible with existing ethics regulations and statutes.
5. **NIH Office of the DHHS General Counsel (OGC)**: provides both formal and informal advice regarding the interpretation and application of NIH policies on activities with outside organizations, other than those related only to ethics issues.
6. **ICD Ethics Coordinators** are responsible for: a) serving as the primary point of contact for the exchange of information on activities with outside organizations and other ethics issues; b) providing the annual ethics report for their organizations; and c) providing administrative and/or program support for ICD Ethics Programs as defined by their Directors and/or Deputy Ethics Counselors.

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7. **Supervisors** are responsible for: a) acquiring a working knowledge of policies, and procedures regarding activities with outside organizations and other ethics activities; b) helping employees understand and comply with these requirements; c) ensuring that job applicants are fully aware of outside activity and other ethics requirements and, if appropriate, resolving any conflicts before employment; d) reviewing requests for outside work and official duty activities and approving those within their authority or making recommendations on the disposition of requests for those that must be approved by their Deputy Ethics Counselor; and e) obtaining assistance from their Ethics Coordinators to fulfill these responsibilities.
 8. **Employees** are responsible for: a) acquiring a working knowledge sufficient to comply with the Government-wide standards of conduct, DHHS supplemental regulations, and NIH policies regarding activities with outside organizations; b) obtaining advice from supervisors and their ICD Ethics Coordinator when needed; c) submitting requests for activities with outside organizations for review and approval prior to the start of the activity; and d) providing all information needed by higher level officials to make well informed decisions about the approval of requests to engage in activities with outside organizations.
- E. EXCEPTIONS TO NIH POLICY:** All requests for exceptions to NIH ethics policies must be fully documented in writing and submitted through the ICD DEC to OHRM for subsequent coordination with OGC/ED. These organizations will make written recommendations on the disposition of exception requests. Specific procedures and approval levels for exceptions are discussed throughout this instruction.
- F. DEFINITIONS:** Many terms used in the standards of conduct and this chapter are legal terms and therefore very specific and important to determining the nature and appropriateness of any activities with outside organizations. The following definitions are provided to assist in the understanding of this chapter:
1. **Conflicts of Interest.** A **real** conflict of interest arises when an employee takes an action which affects the financial interests of the employee, the employee's spouse or the employee's dependent child, or other interests imputed to the employee by law. An **apparent** conflict of interest arises when an employee is involved in a particular matter and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the impartiality of the employee in the matter. The following appendices contain additional information about conflicts of interest:

Appendix 1, Conflicts of Interest

Appendix 2, Appearances of Conflicts of Interest

Appendix 3, Conflicts Arising from Outside Professional Practice

Appendix 4, Employment Negotiations with Non-Federal Organizations

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2. **Cooling-Off Period:** That time after the end of an outside activity during which the employee continues to be disqualified from conducting any official activity with the sponsoring organization of the outside activity.
3. **Direct and Predictable Effect:** The impact that an employee's official duties may have on an outside financial interest which can result in a conflict of interest. A matter will have a direct effect on a financial interest if there is a close causal link between any decision or action taken as official duty and any expected effect of the matter on the employee's financial interest. An effect may be direct even though it does not occur immediately. A particular matter will not have a direct effect on a financial interest, however, if the chain of causation is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter will have a predictable effect if there is a real, as opposed to a speculative, possibility that the matter will affect the financial interest. It is not necessary, however, that the magnitude of the gain or loss be known.
4. **Disqualification or Recusal:** A written statement used to resolve an apparent or actual conflict of interest. It is also called a recusal. An employee signs a statement withdrawing from participation with an organization to remove a real or potential conflict of interest. The disqualification statement also identifies a higher level official who will deal with the matters from which the employee is disqualified. A recusal must be approved by a Deputy Ethics Counselor. See Appendix 5 for a sample recusal.
5. **Fiduciary Duty:** An obligation to act in the best interest of another party. For example, a board member of a corporation has a fiduciary duty to the shareholders, an attorney has a fiduciary duty to a client, or a business owner has a fiduciary responsibility to him/ herself and the business. A fiduciary obligation exists whenever one person places special trust and confidence in another person and relies upon that person to exercise his/her discretion or expertise in acting for the client; and the fiduciary knowingly accepts that trust and confidence and thereafter undertakes to act on behalf of the other when exercising his/her own discretion and expertise. When one person does undertake to act for another in a fiduciary relationship, the law forbids the fiduciary from acting in any manner adverse or contrary to the interests of the client, or from acting for his/her own benefit in relation to the subject matter.
6. **Financial Interest:** Any monetary interest of the employee, his/her spouse and/or dependent children. A financial interest may also arise from service as an officer, employee, trustee or general partner. Such interests include, but are not limited to, stock interests, bank accounts, mutual funds, sector funds, consulting relationships, sources of salaries, and leave of absence agreements. The monetary interest may be present or future (future royalties and patent rights). A financial interest may also arise from service on the Board of Directors of an

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outside organization or from financial interests of a partner or organization in which the employee has a financial interest, such as seeking employment.

7. **Negotiation:** A means of discussion or communication with another person, or such person's agent or intermediary, mutually conducted with a view toward reaching an agreement. The term is not limited to discussions of specific terms and conditions.
8. **Official Duty Activities:** Approved, non-compensated activities with an outside organization carried out by an employee as part of his/her official Government duties and responsibilities. Typically, official duty activities involve ongoing or announced policies, programs, or operations of NIH or DHHS; matters that are or have been assigned within the last 12-month period (and may or may not have been publicly disclosed), rather than the general scientific or professional expertise of the employee; and/or invitations extended primarily because of your official position.
9. **Outside Activities:** Approved activities or work for an outside organization, with or without pay or other compensation, carried out by employees separate from their officially assigned Government responsibilities. These activities involve the employee's general scientific or professional expertise or matters that had been assigned before the previous 12-month period and which have been publicly disclosed.
10. **Outside Organization:** For a civilian employee an outside organization is any non-DHHS organization such as: a non-profit organization including a professional association or society; a university, hospital, or medical center; state or local governments; non-DHHS Federal agencies; and, for profit organizations such as biotechnology firms, pharmaceutical companies, law firms and other industry. For Commissioned Officers, only non-Federal organizations are considered outside organizations. Some outside organizations may be prohibited sources for which outside work may not be authorized. For example, Commissioned Officers may not participate for pay in any activity with a Federal agency or organization which pays fees or salaries from Federal funds.
11. **Particular Matter:** The criminal conflict of interest and post-employment statutes come into play when an employee participates in a particular matter. A particular matter refers to the official action taken by an employee and includes matters that involve a deliberation, decision, or action that is focused upon the interests of specific persons, or a discrete and identifiable class of persons. A particular matter does not need to involve formal parties and may include governmental action such as legislation or policy-making that is narrowly focused on the interests of a discrete and identifiable class of persons.
12. **Personal and Substantial Participation:** Criminal statutes impose restrictions on an employee who participates directly with or has the direct and active supervision of the participation of a subordinate in the matter. To participate substantially means that the

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employee's involvement is of significance to the matter. Participation may be substantial even though it is not determinative of the outcome of a particular matter.

13. **Prohibited Source:** Any person or organization which seeks official action by the employee; does business or seeks to do business with the employee; conducts activities regulated by the employee's agency; and/or has interests that may be substantially affected by the performance or nonperformance of the employee's official duties, or an organization whose members fit into any of the descriptions above. Examples include any organizations with a financial interest such as grants in a portfolio managed by the employee, or cooperative agreements, contracts, a Cooperative Research and Development Agreement (CRADA), or other funding agreements in which the employee is personally involved.
13. **Waiver:** A written determination used to resolve a real conflict of interest. Criminal statutes governing the conduct of federal employees allow the use of a waiver to mitigate the terms of the statute. In this chapter, the term waiver also includes an "authorization," which is used to resolve an apparent conflict of interest. For example, waivers may be used when a spouse has a position that may conflict with an employee's work or when an employee working on a CRADA must obtain a waiver under 18 U.S.C. Section 208 before the employee may negotiate for employment with the outside collaborator. Waivers must be approved by a Deputy Ethics Counselor, the appointing authority (usually the ICD Director) and OGC/ED. Waivers are only issued to allow an employee to participate in an official duty activity, not to permit an outside activity. Samples are contained in Appendices 1 (waiver for real conflict) and 2 (authorization for apparent conflict).

G. ACTIVITIES WITH OUTSIDE ORGANIZATIONS: An NIH employee may participate, with prior approval, in activities with outside organizations in one of the following forms: 1) outside activities in which an employee performs work that is unrelated and separate from his/her assigned duties and responsibilities at NIH; 2) official duty activities in which an employee performs work that is part of, or an extension of, his/her officially assigned duties and responsibilities at NIH; or, 3) in the capacity of a Federal liaison representing the Government's views and interests on policy and program matters. It is important that managers and employees fully understand the differences among these types of activities because there are criteria containing both permissive and restrictive features for each.

Some activities are exempt from the guidelines in this chapter, such as activities which do not involve an employee's work-related professional skills and abilities. Examples of non-work related outside activities include: playing an instrument in an orchestra, appraising antiques, teaching aerobic classes, working in a department or grocery store, or service on a board at a religious or community organization. Employees may engage in these types of activities without prior approval by a supervisor or Deputy Ethics Counselor. Though not necessarily considered outside activities, political activities are governed by the Hatch Act. Employees should consult their DEC or Ethics Coordinator for questions regarding the Hatch Act.

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Though NIH is comprised of predominantly scientific staff, this chapter also covers non-scientific staff. Administrative, computer, law enforcement, and other staff must also compare the focus of any proposed activity with an outside organization to their current official responsibilities to determine the closeness, and work with their DEC to determine whether the activity needs advance approval.

1. **Outside Activities:** An employee may engage in outside activities that require the use of professional qualifications readily identified with his or her NIH position, provided his/her work does not create a real or an apparent conflict of interest or interfere with regularly assigned duties.
 - a. Basic Rules for Outside Activities
 - (1) Activities Must Not Be Related to Official Duties: An employee **may not** receive compensation for outside activities that relate to his/her official duties and responsibilities as an NIH employee. An activity is considered related if it is done as part of official duties or the employee was invited to perform the activity primarily because of the employee's official position, or it deals with any matter to which: an employee is presently assigned; an employee has been assigned during the previous one-year period; or if it deals with any ongoing or announced policy, program or operation of the NIH.

Exception: An employee may teach a course, with or without compensation, on topics related to his/her official duties when that course involves at least two presentations and is offered as part of a regularly scheduled curriculum at an accredited institution of higher education.
 - (2) Compensation: An employee **may** receive compensation for his/her work with outside organizations. Compensation may be in the form of money, stocks, or any other financial instruments that have a monetary value. For teaching, speaking and writing, compensation also includes travel expenses, whether provided in-kind or reimbursed. An employee may also perform work for an outside organization without pay. There is no limitation on the amount of compensation the career employee can receive. Non-career employees should contact their DEC or Ethics Coordinator to determine if they are subject to limitations.
 - (3) Compensation From Federal Agencies: A civilian employee may not accept remuneration for service of any kind that is funded by a DHHS contract, grant, cooperative agreement, or other DHHS mechanism. Compensation is also prohibited for assisting or preparing a grant application or other document intended for submission to the DHHS (5 CFR 5501.106(c)). Compensation for any kind of work performed for and paid directly by another Federal agency may be

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accepted unless prohibited by either the Dual Compensation Clause (5 U.S.C. Section 5533) or the Federal Acquisition Regulations. However, compensation from a Federal grant or contract may be accepted for work performed for a non-DHHS organization provided that: (a) the services performed do not involve legal representation, accounting services or public relations services; and (b) the source of the funding is not DHHS. A Commissioned Officer (CO) may not accept funds provided directly or indirectly by any Federal source other than his/her salary. For example, a CO may not accept payment for private practice from funds reimbursed to the employer by Medicare. Employees are encouraged to check with their DEC or Ethics Coordinator for guidance in specific situations.

- (4) Use of Personal Time: An employee must conduct all outside activities on his/her personal time. If outside work is to be performed during normal NIH working hours, the employee must be on approved annual leave, leave without pay, credit hours, or compensatory time and not present at his/her duty station. There is no limit on the number of hours an employee can devote to outside activities except when time spent on outside activities interferes with the performance of an employee's official duties.

A Commissioned Officer is required to take one day of annual leave for any portion of a day during which an outside activity takes place.

- (5) Use of Government Resources: An employee may not use government resources (e.g., equipment, services, stationary or other supplies or staff) in the performance of outside activities.
- (6) Use of NIH Space: An employee may not normally use NIH meeting rooms for outside activities. Occasionally, activities may be authorized if they are a part of an NIH event which has been approved by the Office of Research Services for the use of NIH space. However, exceptions will be approved only if it is determined that the activities will serve an important need of NIH.
- (7) Use of Official Titles: Both the employee and an outside organization are prohibited from referencing the title of an employee in connection with any outside activity or employment except as follows:
- (a) An employee may include or permit the inclusion of his/her title or position as one of several biographical details when such information is used to introduce and identify the employee with the outside activity, provided the title or position is given no more prominence than other significant biographical details. However, it does **not** mean that an employee may be listed in the written program using title and Institute affiliation. If

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employees see an improper listing, it is advised that they write to the organization and include the Standards of Ethical Conduct rule in the correspondence. This will help protect the employee and avoid any problems. In addition, when giving oral presentations, employees should inform their audience that they are speaking in a personal capacity and the opinions expressed are their own and do not represent the views of the Federal Government.

- (b) When a title or position is used in connection with articles published in a scientific or professional journal, or other publication where the topics relate to research, the title or position may be used but must be accompanied by a reasonably prominent **disclaimer** that the views expressed in the articles do not necessarily represent the views of NIH and/or DHHS, for example: "This article [chapter] was written in a personal capacity and does not represent the opinions of the NIH, DHHS, or the Federal Government."
- (8) Use of Information on Current and Ongoing NIH Research: In the context of an outside activity, only information that is in the public domain may be used and that information must not derive from work an employee has done within the last year. An employee may provide information on previous work (i.e., performed prior to the last 12-month period) which has been publicly disclosed, provided such information is not the subject of ongoing research, programs, or policies. The employee may also provide information that is based on his/her general scientific or professional knowledge and expertise and not derived specifically from his/her employment at NIH.
- (9) Advance Approval Required: All outside activities must be requested and approved in advance by a Deputy Ethics Counselor or authorized designee as authorized by current personnel delegations of authority (most recent version dated 2/21/96 as of the date of this issuance).
- (10) Participation in the Business Affairs of Outside Organizations: An employee may participate in the internal and external business operations of an outside organization as an outside activity, including involvement in the human resources, financial or fund-raising activities to the extent permitted by these organizations. Such involvement usually occurs when an employee serves as an officer or member of a Board of Directors of an outside organization. However, such service may require that the employee disqualify him/herself if the outside organization has any official connections to the employee's official position at NIH.

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- (11) Other Considerations Associated With Working for an Outside Organization: There is no limit on the amount of money an employee may earn from outside work activities. There is also no limit on the amount of time an employee can spend performing outside activities. However, outside activities may not interfere or impair the ability of an employee to perform his/her officially assigned Government duties. Approval to engage in outside work activities will be denied or withdrawn if the activities interfere with the performance of the employee's duties at NIH or those of his/her co-workers.
 - (12) Activities With Foreign Entities: The US Constitution prohibits Federal Government employees from holding any position with a foreign government, including any entity funded or run by a foreign government. Therefore, employees may not have an outside activity with any foreign government nor with any organization funded or run by a foreign government, for example a foreign university which is funded by the foreign government. Outside activities with privately funded foreign universities and other foreign entities are permissible.
- b. Types of Outside Activities: Within this framework, the following types of compensated assignments may be permitted as outside activities:
- (1) Writing or editing textbooks or other scientific or professional books;
 - (2) Editing scientific or professional journals or reviewing manuscripts, including service on a editorial board;
 - (3) Teaching;
 - (4) Consulting with organizations when the primary purpose is to render scientific or professional advice based on the scientist's personal expertise. Examples include consulting for a law firm, in a review and evaluation context, in the format of a round table discussion, or as a self-employed consultant.
 - (5) Serving on scientific advisory or review boards to render advice on scientific or educational matters; [If the service is on an advisory board of a for-profit organization, NIH employees may not comprise more than one-third of the board's membership. If the advisory board or editorial board actually makes a decision on whether policy will be implemented or specific scientific papers will be published, then membership on the board must be performed as an outside activity.]

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- (6) Engaging in outside practice within the employee's profession, such as clinical practice by physicians, dentists, nurses and other licensed health professionals, provided there is no conflict of interest or commitment to patient care during work hours; or
- (7) Giving formal speeches or presentations on a scientific or professional topic based on the employee's personal expertise.

The following appendices contain additional information on outside activities:

Appendix 6, Summary Information on Activities with Outside Organizations
Appendix 7, Detailed Information on Writing, Editing and Consulting
Appendix 8, Examples of Activities with Outside Organizations

- c. Continuing Outside Activities: Outside activities with an original approval period equal to or greater than one year are considered continuing outside activities, and are required to be updated annually. Though use of the HHS Form 521 is no longer required, the information contained on the form is required, i.e, whether the activity is still continuing and the number of hours the employee was engaged in the outside activity. ICDs are required to obtain the updated information at the beginning of each calendar year and may use the HHS-521 or other format to collect the information. Reporting period is the previous calendar year. No further reporting of the information to the NIH is required.
2. **Official Duty Activities:** An employee may participate in activities with outside organizations when the service he/she provides is a part, or an extension, of his/her regular duties and responsibilities at NIH.
- a. Basic Guidelines for Official Duty Activities With Outside Organizations
 - (1) Activities Related to Official Duties: The activities an employee performs must be related to his/her official duties. Any official work performed with an outside organization must also be consistent with the authority and mission of NIH. There should be compelling agency policy reasons for official duty activities with outside organizations. Such activity should be avoided if the outside organization engages in lobbying or otherwise takes public positions on matters of significant controversy involving the NIH. Such activity should be limited where it is likely that the outside organization may become involved in legal disputes or other actions (e.g., medical care, personnel) that could subject it to liability. Because the activities are related to the employee's job, the employee may use non-confidential official information:

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- (a) that is available to the public or necessary to the work at hand, including information drawn from his/her current work or any work performed within the last 12-month period;
 - (b) associated with previous work (i.e., any matter in which the employee was involved prior to the last 12-months) regardless of whether it has or has not been publicly disclosed; and,
 - (c) that involves any on-going or announced NIH policy, program or operation (rather than the outside organization's or the employee's general scientific or professional knowledge).
- (2) Compensation: An employee is compensated by the Federal government for performing his/her official duties. Therefore, an employee may not accept any form of compensation from an outside organization or source for performing his/her official duties. This does not include travel or per diem expenses which may be allowable with prior approval through the HHS-348 sponsored travel process. Acceptance of monetary awards may be permissible (see also the section entitled "Acceptance of Awards and Honorary Degrees").
- (3) Official Time: An employee who performs his/her officially assigned duties and responsibilities with outside organizations is working on official time and therefore he/she is not required to take annual leave or leave without pay.
- (4) Use of Government Resources: An employee may use Government equipment, supplies, services, and staff to carry out his/her assigned duties with outside organizations. The employee travels using Government travel orders, and may travel on an approved HHS-348 if applicable.
- (5) Use of NIH Space: An employee may use NIH space and facilities when needed to accomplish official duty work with an outside organization. Meeting rooms and other space must be requested in the same manner as for any internal NIH function.
- (6) Use of Official Titles: Outside organizations may use the official titles of an employee as a reference, identifier, or to promote attendance at public meetings or presentations, when the employee is participating in an official capacity.
- (7) Official Duty and Outside Activities with the Same Organization: An employee usually may not engage in official duty activities while, at the same time, engage in outside activities with the same organization.

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Exception - An employee may perform outside activities and official duty activities with the same outside organization during the same time period if:

- (a) the outside activity involves: a position (elected or not) in the organization, i.e., professional association; or an appointment to an academic/medical institution with no compensation or minimal compensation and limited teaching responsibilities; and
 - (b) the official duty involves the presentation of research related information; and
 - (c) the employee obtains a waiver from his/her Deputy Ethics Counselor when the determination is made that the conflicting financial interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from the employee. A signed waiver must accompany both outside activity requests and requests for payment-in-kind (HHS-348). Appendices 1 and 2 contain sample waiver and authorization requests.
- (8) Advance Approval Required: Official duty activities must be requested and approved before an employee can participate in an activity with an outside organization. Deputy Ethics Counselors must approve official duty requests, although consistent with the delegation of authority, they may delegate to supervisors the authority to approve short term official duty activities (e.g., less than a year) with outside organizations, such as participating in or organizing a scientific symposium or seminar, or presenting speeches at public events that are related to the employee's own research conducted within the last 12-month period. Each ICD may determine whether such permission will be given verbally or in writing.
- (9) Participation in the Business Affairs of Outside Organizations: An employee performing an official duty activity may not participate in making decisions or taking actions that affect the internal business affairs of the organization, including:
- (a) personnel actions regarding the staff of the organization and/or establishing their compensation and benefits;
 - (b) the financial management of the organization, including sources and disposition of the income of the organization, management of investment portfolios, or other related matters; or,

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- (c) fund-raising activities.
- b. Types of Official Duty Activities: The following activities are examples of acceptable official duty activities at NIH:
- (1) Service on Scientific Advisory or Review Boards: An employee may serve without compensation on scientific advisory and review boards with Federal, university, or private sector organizations to render advice on scientific or educational matters. In addition, an employee's participation must involve only providing advice and/or making non-binding recommendations. If the advisory board or editorial review board actually makes binding decisions on whether policy will be implemented or specific scientific papers will be published, then membership on the board must be performed as an outside activity, or the employee must have a waiver. See Appendix 1, Sample 2, for a sample waiver. This activity may also be performed as a Federal Liaison (see section 3. Federal Liaison Activities, below).
 - (2) Writing and Editing: An employee may write books, chapters, forewords, articles, or edit scientific articles and journals in his or her area of professional or scientific expertise for nonprofit outside organizations without compensation.
 - (3) Speaking and Lecturing: An employee may give uncompensated speeches or lectures at meetings, seminars, and other gatherings open to the public. The topics may come from the employee's general scientific or professional expertise or past or present work at NIH. With appropriate impact on the NIH mission and approval, some uncompensated teaching or lecturing may be done as an official duty activity. See Appendix 9 for information on invitations to widely attended gatherings.
 - (4) Service as Members of Boards of Directors: Based on recent rulings by the Department of Justice and the Office of Government Ethics, employees incur a fiduciary responsibility when they serve as a member of a Board of Directors (elected or not) for an outside organization or professional association as part of his/her official duties. This presents a conflict of interest, and as such, it prohibits a federal employee from serving in an official capacity as an officer, director, board member, or trustee of an outside organization **unless** the employee fits **one** of the following:
 - (a) Serves in the capacity of a non-voting, Federal liaison to the organization's Board of Directors. As a Federal liaison, the employee would be the official DHHS/NIH representative to the organization, and would present and receive information and views on behalf of DHHS/NIH. The employee

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would not serve as an officer or director of the outside organization. The employee could also coordinate joint activities of NIH and the outside organization. As Federal liaison, the employee may not be concerned or involved with the internal business affairs of the organization. The liaison's only duty is to the Government.

- (b) Receives a waiver under 18 U.S.C. Section 208 (b). An employee may receive a waiver upon a written determination that the conflicting financial interest is not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect of the employee. See Appendix 1 for a sample waiver.
- (c) Serves in this capacity on his/her own time as an outside activity.

3. **Federal Liaison Activities:** For some activities with outside organizations, it is important that an employee formally represent the interests of NIH. When an employee is asked to serve as a spokesperson for NIH policies or programs with an outside organization, he/she is designated as a Federal liaison to the organization.
 - a. A Federal liaison must serve as a non-voting, non-fiduciary agency representative to the outside organization.
 - b. An employee serving in this capacity must not participate in the internal or business affairs, or fund-raising activities of the outside organization.
 - c. For all other purposes, the employee is subject to the same provisions that apply to NIH employees engaged in official duty activities.
 - d. An employee may participate as a Federal liaison on Government time, use Government equipment and services, and travel on Government travel orders.
 - e. As a Federal liaison, an employee may serve as a member of a scientific advisory or review board (see section 1. Service on Scientific Advisory or Review Boards, above).
4. Acceptance of Awards and Honorary Degrees: The NIH recommends that awards and honorary degrees be accepted on either official duty or on personal time. No outside activity request is needed. An employee may receive most monetary or nonmonetary awards and honorary degrees given for the employee's professional contributions and/or accomplishments within the employee's respective career or occupational field. More information on these topics is contained in:

Appendix 10, Guidance on the Acceptance of Awards.

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5. Seeking Other Employment: Seeking other employment may sometimes cause a real or apparent conflict of interest with your official duties. In such cases, either a waiver/ authorization or recusal may be necessary. In addition, Federal employees are subject to some restrictions following their departure from the Federal Government. See the following appendices or contact your DEC or Ethics Coordinator for additional information if you are seeking other employment:

Appendix 4, Employment Negotiations with Non-Federal Organizations

Appendix 12, Post-Employment Restrictions

- H. ACTIVITIES WHICH REQUIRE PRIOR APPROVAL:** Employees with proposed outside activities which require approval (i.e., those activities which use professional competence that is identified with their NIH position), must obtain advance approval prior to commencing the activities. The requirements of NIH assignments vary sufficiently such that outside work appropriate in one assignment may not be appropriate in another assignment. All outside activities with outside organizations require higher level approval before the activities begin. DHHS requires an employee to submit Form HHS-520, Request for Approval of Outside Activity, for review and approval before engaging in activities with outside organizations. See Appendix 13 for detailed instructions for requesting approval of an outside activity and illustrations of forms. Activities subject to prior review and approval include:

1. Teaching, lecturing, and speech making;
2. Providing professional and consultative services to outside organizations;
3. Outside professional practice;
4. Consultative services relating to patient care;
5. Service on a board or committee, or holding office in a professional organization;
6. Writing, editing, and publishing;
7. Accepting awards or honorary degrees from outside organizations; and,
8. Other activities which specifically employ the general professional expertise related to the employee's NIH responsibilities.

- I. PROGRAM EVALUATION:** The Office of Human Resources Management will periodically review activities with outside organizations as part of its management control review

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responsibilities. Information obtained from these reviews will be used to identify and resolve any problems and to provide better guidance to NIH employees and managers.

- J. RECORDS RETENTION and DISPOSAL:** Records pertaining to outside work are retained and disposed of under the authority of NIH Manual 1743 "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, Item 2300-730-7b, as follows: Deputy Ethics Counselors must retain original copies of all Form HHS-520s for a minimum of six years after the termination of the activity, except that documents needed in an on-going investigation will be retained until no longer needed in the investigation, or six years after termination of the activity, which ever is later. Copies of approved Form HHS-520s will be returned to the employee.
- K. ADDITIONAL INFORMATION:** Since the operating procedures and practices of employees participating in activities with outside organization differs from one ICD to another, employees should direct their questions to their ICD Ethics Coordinator or Deputy Ethics Counselor (the names and phone numbers of your Counselor and Coordinator can be obtained by calling the Executive Office of your ICD).

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CONFLICTS of INTEREST

General Standards Regarding Conflicts of Interest: Activities with outside organizations can sometimes result in an employee conducting official business with an outside organization in which the employee has a financial interest. Such an interest in an outside organization can lead to conflicts of interests. These conflicts of interest must be mitigated or resolved before an employee may participate in any activities with those organizations. The following guidelines are to be followed to mitigate conflicts of interest.

1. An employee is prohibited from consulting with, lecturing for, or engaging in any other kind of outside activity with outside organizations that: 1) have entered into, or are in the process of negotiating CRADA or any other research agreements, including informal collaborations or research, Material Transfer Agreements, collaborative or otherwise, with the employee's laboratory/branch, or: 2) have received, or are in the process of applying for or negotiating, contracts or other funding from the employee's laboratory/branch if the employee is working on or involved in these matters, e.g., supervising others who work on these matters.

Contracts include supply contracts for the purchase of equipment. Other funding arrangements include any direct or indirect support of staff, guest researchers, special volunteers, or other individuals.

"Laboratory/branch" is defined as an organizational unit within a Division within an ICD. In this context, a laboratory/branch would not be a physical entity consisting of a certain number of employees, nor limited to the intramural arena, but rather a designated part of the ICD organization.

2. Conversely, an employee may not negotiate a CRADA or discuss arrangements for official collaborations with an outside entity in which the employee has an approved outside activity or has some financial interest (e.g., stock ownership). In this situation, the outside activity must be discontinued and/or the issue of stock ownership resolved before any official discussions of potential collaboration may ensue. An appropriate resolution might be a determination that an appearance of conflict is minimal or that disqualification is appropriate.
3. An extramural employee is prohibited from performing an activity for an outside organization when that organization is one that the employee deals with in his or her official capacity. For example, if a Health Scientist Administrator (HSA) manages a portfolio of grants, which includes the University of Virginia, the HSA may not accept an offer to consult with the staff of the University of Virginia unless the employee recuses his/herself from all official business dealings with the University of Virginia.
4. Companies from which NIH procures equipment, services, or supplies are prohibited sources. A violation of 18 U.S.C. Section 208, governing criminal conflicts of interest, may occur when an

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employee has a financial interest in a company from which the employee orders equipment or supplies, even if the company is a sole source supplier.

If an employee has an outside financial interest in a company from which the employee's laboratory orders equipment or supplies, the employee may not participate personally or substantially in the ordering process, unless the employee owns stock in the amount of \$5000 or less in the company in which the orders are placed. Waivers are not recommended where the outside financial interest is an outside activity with a company from which equipment or supplies are needed.

5. A waiver may be requested to mitigate some conflicts when an employee's involvement with an outside organization is determined to be inconsequential and the official business dealings the employee will have with the outside organization are not likely to adversely affect the integrity with which the employee performs his/her job. Waivers may also be appropriate for official duty activities in which an employee has an involvement with an outside organization that involves pension plans, spousal employment or certain financial interests. It is NIH policy that waivers to conduct an outside activity are not routinely granted. A waiver of the provisions of Section 208 (the criminal conflict of interest statute) must be sought from the employee's appointing authority. Generally the ICD Director will be the employee's appointing authority. Waivers can only be authorized on a case-by-case basis.
6. All waivers issued under 18 U.S.C. 208 must be reviewed and approved by the Office of the General Counsel, Ethics Division, at NIH and the Office of Government Ethics.
7. Sample 18 U.S.C. 208 (b)(1) waivers are provided on the following pages:
 - Sample 1: Standard 208(b) waiver
 - Sample 2: 208(b) Waiver for Service as an Officer or Director in an Official Capacity

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SAMPLE 1: Standard 208 (b)(1) Waiver

[Date]

MEMORANDUM

TO: Name of Employee's Appointing Authority]

FROM: [Name of the Employee or Deputy Ethics Counselor]

SUBJECT: Conflict of Interest Waiver for [Employee's Name]

The purpose of this memorandum is to request that you grant a waiver from the provisions of the conflict of interest law, 18 U.S.C. 208(a), for [**name of employee**]. The need for a waiver is discussed below.

Section 208 prohibits federal Executive Branch employees from participating personally and substantially as Government employees in matters in which any of the following individuals or organizations has a financial interest: (1) the employee; (2) the employee's spouse; (3) the employee's minor child; (4) an organization in which the employee serves as an officer, director, trustee, partner, or employee; or (5) a person or organization with which the employee is negotiating for prospective employment or has an arrangement for prospective employment. Pursuant to Section 208(b)(1), however, a waiver may be granted by you after disclosure of the interest by [**the employee**], if you determine that "the interest is not so substantial as to be deemed likely to affect the integrity of the services which the government may expect from" [**the employee**].

[Insert here a paragraph describing the facts in this case.]

Example for employment negotiations: Dr. Doe is working on a CRADA with Company A. Dr. Doe has indicated that he is interested in initiating discussions with Company A regarding possible employment opportunities with Company A. Dr. Doe cannot, under Section 208, begin such discussions unless he first obtains a waiver. Without a waiver, Dr. Doe would be subject to criminal liability under the statute. *(See Appendix 4 for information concerning conflicts associated with employment negotiations.)*

Example for other financial interests: Dr. Doe is an extramural employee approving grants to Universities including the Massachusetts Institute of Technology [MIT]. Dr. Doe's wife formerly worked for MIT and still has a pension plan with MIT. [In this situation, one could reasonably say that Dr. Doe's service to the government will not be impaired by the fact that his spouse has a pension plan with MIT.]

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CHOOSE APPROPRIATE PARAGRAPH

I believe that it would be appropriate for you to grant [**employee name**] a waiver under Section 208(b)(1) to enable him to continue to work on the research end of the CRADA and at the same time pursue employment negotiations with [Company A].

OR

I believe that it would be appropriate for you to grant [**employee name**] a waiver under Section 208(b)(1) to enable him to continue to approve and administer grants to universities, including MIT, despite the conflict created by his wife's pension plan with MIT.

DECISION

___ Waiver granted based on my determination, made in accordance with 18 U.S.C. Section 208 (b)(1) that the interest is not so substantial as to be deemed likely to affect the integrity of the services which the government may expect from [**employee name**].

___ Waiver denied.

[Appointing Authority] _____ [Date]

Confirmed and Acknowledged:

[Employee or Deputy Ethics Counselor] _____ [Date]

Concurrence

[Office of the General Counsel,
Ethics Division, NIH] _____ [Date]

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**SAMPLE 2: 208(B)(1) Waiver for Service as an
Officer or Director in an Official Capacity**

[Date]

MEMORANDUM

TO: [Official with Waiver Authority]

FROM: [Deputy Ethics Counselor]

SUBJECT: Conflict of Interest Waiver for [Employee]

The purpose of this memorandum is to request that you grant [name of employee] a waiver of the criminal conflict of interest provisions that may apply to [his or her] service in an official capacity as [an officer or a member of the board of directors, or other position] of an outside non-profit organization. The need for a waiver is discussed below.

The criminal conflict of interest statute, 18 U.S.C. § 208(a), requires that an employee refrain from participating personally and substantially in an official capacity in any particular matter that will have a direct and predictable effect on the financial interests of any organization in which the individual serves as an officer, director, trustee, or employee.

In the absence of: (1) specific statutory authority placing a federal employee in an officer or director position in an ex officio capacity, (2) a release of fiduciary obligations by the organization (if permitted by state law), or (3) a waiver of the requirements of section 208(a), the conflicts statute effectively would preclude [the employee's] service, as an official duty activity, as [officer, director, or other position] of [name of organization].

[Describe position and organization.] [Describe relationship of organization, if any, to Departmental programs or operations.]

Inasmuch as [the employee's] [appointment, election, or selection] as [officer, director, or other position] of [name of organization] is not pursuant to a statute or release of fiduciary obligations, [he or she] has requested that you, as the official responsible for [his or her] appointment to a federal position or the official to whom waiver authority is delegated, authorize [his or her] participation in certain particular matters that may affect the financial interests of [name of organization]. Under section 208(b)(1), a waiver may be granted if the selecting official or delegatee determines that the disclosed financial interest is "not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from ... [the] employee."

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In the course of [his or her] assigned duties as [employee's government title], the following types of particular matters potentially could come before [the employee] for [his or her] personal and substantial participation: (1) particular matters of general applicability, such as legislation, regulations, or policy, that may affect the financial interest of [name of organization] as a member of a class of similarly situated entities; (2) matters that affect one or more of the underlying holdings in the investment portfolio of [name of organization]; (3) particular matters involving specific parties (specific party matters), such as grants, contracts, application approvals, litigation, investigations, or enforcement actions, that specifically involve [name of organization] or otherwise affect its financial interest; or (4) other miscellaneous matters involving the conduct of the organization's affairs and Department support.

While performing, as an official duty activity, the usual and customary duties of the position of [an officer or a director or another position] of an outside organization, any actions taken, either in the federal workplace or at the organization, that affect the financial interest of the outside organization are deemed official matters to which section 208(a) may apply. For example, such actions may include: (1) requesting that official travel funds be spent or other government resources be utilized for the employee to conduct the affairs of the organization; (2) signing a training authorization to use agency funds to pay for a subordinate to attend a seminar or other meeting of the organization; (3) speaking as an official duty activity, or directing a subordinate to speak, at any seminar or other meeting of the organization where attendance fees are charged; (4) participating as an official duty activity in fund-raising activities of the organization; or (5) providing advice and consultation with respect to, or otherwise conducting, the business affairs of the organization. While the financial impact of many of these particular matters on an outside organization may be insignificant, under well settled precedent, section 208(a) has no de minimis aspect (dollar level under which, by definition, conflict is not considered to exist or is so minimal as to have no impact).

Accordingly, if approved, the requested waiver will apply fully to the employee's participation in an official capacity in any particular matter that will directly and predictably affect the financial interest of [name of organization], EXCEPT the following particular matters, as to which [the employee] [has recused or has committed to recuse]:

[Identify particular matters to which the waiver is NOT intended to apply, e.g., grants to or contracts with the outside organization. In unique circumstances, a waiver might be appropriate for participation in a grant, contract, or other specific party matter. But absent a strong justification, such matters are likely to be standard exceptions to this waiver for which a recusal will be required. If no exceptions are intended, state "None" at this point in the document and describe below the justification in detail.]

I believe that a waiver is justified for the following reasons:

First, because [the employee] would serve in [the outside organization] as an assigned official duty activity, there is a greatly diminished risk that the integrity of the services that the Government expects would be affected. [The employee's] position in the outside organization is fully known to the agency.

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Moreover, the agency already has determined that, to a significant degree, the interests of the Department and the interests of **[the organization]** are consonant; the agency expects that the interests of the Department and the interests of **[the organization]** both can be furthered through the performance of **[the employee's]** official duties.

Second, most if not all of the particular matters in which **[the employee]** would participate would not have a significant effect on the financial interests of **[the organization]**. **[If the employee will have no involvement in any HHS grants, contracts or other financial support to the organization--other than the use of Government travel or training funds--and will not be involved in regulatory or investigatory matters having a significant financial impact on the organization, state this fact here.]**

[If the employee is expected to be involved in more problematic matters that involve funding of the organization or regulatory or investigatory matters that significantly affect the financial interests of the organization, a stronger justification for a waiver would be needed. Such matters can pose a greater risk of a conflict of interest, and consequently the justification for a waiver in such cases would have to be explained in greater detail. Any information bearing on the magnitude of the financial impact (for example, the size of a grant or contract) would be relevant. Also, it may help to discuss any limits on the employee's involvement in the matter (for example, whether the employee is subject to significant supervision or is only involved in a limited aspect of the matter). Moreover, if the matter involved a regulation, policy statement or other matter of general applicability, this should be noted, as such matters typically are less problematic.]

The employee understands and agrees that, as an official duty activity, no separate compensation may be received from the outside organization in connection with **[his or her]** service as its **[officer, director or other position]**.

[State any other facts, commitments, terms, or conditions relevant to the appointing official's assessment of the request.]

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DECISION:

___ Waiver granted, subject to the terms and conditions stated above, based on my determination, made in accordance with 18 U.S.C. § 208(b)(1), that the disclosed financial interests are not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect from the employee.

___ Waiver denied.

[Name of selecting official or delegatee]

[Title]

Date

Confirmed and Acknowledged:

[Name of employee]

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APPEARANCES of CONFLICTS of INTEREST

The appearance of a conflict of interest arises where an employee is involved in an official duty capacity with specific outside parties and there are circumstances that would cause a reasonable person with knowledge of the relevant facts to question the employee's impartiality in the official matter. Specific outside parties may include:

1. A member of the employee's household or a relative with whom the employee has a close personal relationship;
2. A person or organization with whom the employee has or seeks a business, contractual or other financial relationship that involves other than a routine consumer transaction;
3. A person or organization for whom the employee's spouse, parent or dependent child is, to the employee's knowledge, serving or seeking to serve as an officer, director, trustee, general partner, agent, attorney, consultant, contractor or employee;
4. A person or organization for whom the employee has, within the last year, served as an officer, director, trustee, general partner, agency, attorney, consultant, contractor or employee; or
5. An organization in which the employee is an active participant (e.g., serves as a committee chair, spokesperson, promotes the organization, coordinates fund-raising events).

It is the responsibility of the ICD Deputy Ethics Counselor to determine whether the employee should be authorized to participate in the matter. The ICD Deputy Ethics Counselor may determine that the employee's impartiality is likely to be questioned and the employee should not participate in the matter. The ICD Deputy Ethics Counselor may, alternatively, determine that any question of impartiality is insignificant and a waiver of the appearance of conflict of interest should be given, thereby authorizing the employee to participate in the matter.

The ICD Deputy Ethics Counselor must find that, in light of all relevant circumstances, the Government's interest in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations.

The following factors should be considered in making a decision whether the employee should participate in the matter:

1. The nature of the relationship involved;
2. The effect that the resolution of the matter would have upon the financial interests of the employee involved in the relationship;

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3. The nature and importance of the employee's role in the matter, including the extent to which the employee is called upon to exercise discretion in the matter;
4. The sensitivity of the matter;
5. The difficulty of reassigning the matter to another employee; and
6. Adjustments that may be made in the employee's duties that would reduce or eliminate the likelihood that a reasonable person would question the employee's impartiality.

An authorization to participate shall be documented in writing at the discretion of the ICD Deputy Ethics Counselor or when requested by the employee. A sample authorization follows.

Note: This section derives from Section 2635.502 of the Standards of Ethical Conduct for Executive Branch Employees.

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**Sample 502 Authorization for
Appearance of Conflict of Interest**

[Date]

MEMORANDUM

TO: [Name of Employee's Deputy Ethics Counselor or Designee]

FROM: [Name of Employee]

SUBJECT: Authorization to Participate Under Section 502

I am writing to request authorization to participate in an official duty matter notwithstanding the conflict of interest provisions set forth in 5 C.F.R. § 2635.502. Section 2635.502 (a) states, in part:

"Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his/her household, or knows that a person with whom he has a covered relationship is or represents a party to such a matter, and where the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his/her impartiality in the matter, the employee should not participate in the matter until he has informed the agency designee of the appearance problem and received authorization from the agency designee..."

Authorization under section 2635.502 (d) may be granted by the ICD Deputy Ethics Counselor (agency designee) where

"..an employee's participation in a particular matter involving specific parties would not violate 18 U.S.C. § 208 (a), but would raise a question in the mind of a reasonable person about his/her impartiality,"

but,

"the interest of the Government in the employee's participation outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations."

[Insert here the facts that raise an appearance of a conflict of interest. For example, John Doe is an employee of a laboratory at the National Cancer Institute that is negotiating a collaborative research and development agreement (CRADA) with Bristol Myers. John Doe's brother is a senior vice-president at Bristol Myers. While John Doe is a scientist and will work on the CRADA, he will have no role in negotiating the CRADA nor will he have any oversight responsibilities over Bristol Myers' collaboration

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with this lab. For these reasons, I believe a waiver of any appearance of conflict of interest is appropriate.]

Important: Employees who have served in outside organizations (e.g., consultant, employee, board member) in the last year may not participate in official matters involving these entities for one year. The Deputy Ethics Counselor (DEC) may determine that a shorter period would be appropriate given an evaluation of the specific facts of each case. The DEC should state in the waiver that official participation is allowed after one year or after a shorter period as determined by the DEC.

DECISION:

_____ Authorization to participate granted based on my determination, made in accordance with section 2635.502(d), that "the need for the individual's services outweighs the concern that a reasonable person may question the integrity of the agency's programs and operations."

_____ Authorization to participate denied.

Deputy Ethics Counselor

Date

Confirmed:

Employee

Date

Concurrence:

Office of the General Counsel,
Ethics Division, at NIH

Date

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CONFLICTS ARISING FROM OUTSIDE PROFESSIONAL PRACTICE

NIH physicians, dentists, psychologists, social workers, nurses, and other licensed health professionals may engage in outside professional practice subject to the following guidelines:

1. The practice must be authorized by the ICD Deputy Ethics Counselor (or by the Deputy Director, NIH, in the case of ICD Directors and OD personnel), who must certify that there is no conflict of interest or conflict of commitment between the conduct of outside professional practice and the interests of NIH. A "conflict of interest" means a situation where the employee has a personal or imputed financial dealing with an outside organization, and deals with the organization as a part of his/her official duties (e.g., contract, CRADA or an official duty activity). A "conflict of commitment" means a situation where the outside work is of such a nature that it would interfere with the employee's ability to perform fully his or her NIH duties.
2. The practice may be allowed only in non-Government locations, such as HMOs, emergency rooms, clinics, or other private settings (clinical activity conducted in space contracted by the Government is considered a Government location). The practice must be defined and approved in advance, with assurance that:
 - a. Outside patient support is provided by someone other than the NIH employee for patients during the NIH employee's official working hours, and will specifically include coverage for emergencies and acutely-ill patients; and
 - b. The NIH employee will not have outside patient contact, including telephone calls, during official working hours.
3. The practice will be conducted under the condition that NIH patients may not be referred to the private practice of an NIH employee, nor from such practice to the NIH, and that patients be informed in advance of this policy.
4. An employee requesting approval to engage in private professional practice must agree that:
 - a. No patient with whom a continuing health professional-patient relationship is established in an outside professional practice, will be referred to the NIH as either an in-patient or out-patient as a consequence of that relationship.
 - b. The employee will never knowingly establish a physician-patient relationship in outside private practice with any current or recently discharged NIH patient.
 - c. No employee with final responsibility for the admission of patients to the Clinical Center may receive a fee for service as a consultant to another physician where the condition of the

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patient would appear to make the patient eligible for Clinical Center admission in an area currently supervised by that employee.

- d. An employee will not accept primary responsibility for the care of one or more patients except in circumstances where it will clearly not impose on, or interfere with, his/her responsibilities as a Federal employee.
5. Any employee engaging in private practice for the purpose of maintaining professional credentials must obtain a letter from the NIH Office of the DHHS General Counsel stating that they are covered by the Federal Torts Claims Act for any patient care activities in which the employee will be involved as part of official duties. The employee may also obtain personal malpractice insurance.
6. Commissioned Corps Officers are specifically prohibited from receiving compensation from other Federal agencies for outside private practice, including fees from private practice that are reimbursed by Federal funds, such as Medicare.

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OUTSIDE WORK, FINANCIAL INTEREST AND RELATED ACTIVITIES

EMPLOYMENT NEGOTIATIONS WITH NON-FEDERAL ORGANIZATIONS

Employees may encounter conflicts of interest when they seek non-Federal employment. Employees seeking employment outside the Federal Government, or who are interested in negotiating for non-government employment, are affected by restrictions contained in 18 U.S.C. Section 208, the criminal conflict of interest statute, and by restrictions contained in the Office of Government Ethics Standards of Ethical Conduct for Employees of the Executive Branch (effective February 3, 1993). This section provides definitions of relevant terminology, general rules to follow during the employment negotiation process, disqualification requirements, and conditions for obtaining a waiver.

1. DEFINITIONS

- a. Employment: In the context of negotiations, employment includes work of a continuing nature in any potential non-Federal position. This includes, but is not limited to, employment involving contracting arrangements, consulting, board memberships (whether or not compensated), or other positions. Examples of potential employers include professional or trade associations, universities, nonprofit corporations, for-profit companies, and international organizations.
- b. Seeking Employment: The process of "seeking employment" begins with the solicited or unsolicited communication with a particular organization by an employee regarding possible employment. An employee is considered to be seeking employment when sending a targeted resume to a person or organization with whom he or she is in regular contact in the course of official duties. The employee is not considered seeking employment when sending an unsolicited resume to a person affected only as a member of a class or similarly situated persons. For example, if an NIH employee was working on a line of investigation and the results are of interest to many biotechnology companies, the employee could send an unsolicited resume to any of these companies. On the other hand, if the employee was working on a line of investigation that uniquely and distinctly affects just one biotechnology firm, the exception would not apply--sending a resume to that company becomes seeking employment. The process of seeking employment terminates once the employee receives or gives a rejection of an offer, or if two months have passed since the unsolicited resume was sent and no response has been received. Deferring discussion of an offer is still considered seeking employment.
- c. Negotiating employment: Any bilateral discussions or communications with a person or organization with a view toward possible employment. Negotiating employment ends when either the employee or the potential employer rejects the terms and terminates the discussions.
- d. Disqualification: A disqualification (also known as recusal) removes the employee from any official responsibility associated with the potential employer; it may be done either in writing

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or simply by the employee withdrawing from participation with the potential employer. In the latter case, the employee's supervisor must be apprized of the disqualification.

- e. Waiver: A waiver is written permission to continue to conduct official duties despite another non-official relationship with the same organization because the employee's financial interest is not so substantial as to affect the integrity or the employee's services to the Government. A waiver of the conflict of interest statute, 18 U.S.C. 208, may be granted by the employee's Deputy Ethics Counselor. An **authorization** under 5 CFR 2635.502 of the Standards of Ethical Conduct may be granted to permit the employee to participate in a matter affecting a person with whom the employee has sought employment.

2. GENERAL RULES

- a. Seeking or negotiating for employment must be performed on the employee's personal time. It is not considered an outside activity nor may it be done as part of the employee's official duties. Therefore, the employee does not need to file an HHS Form 520 for the job search or interview.
- b. An employee may give a lecture as part of employment negotiations with an outside entity but may not accept compensation for the lecture. Accepting compensation for the lecture would convert the job interview into an outside activity. In this case, the employee must request advance approval via an HHS-520, Request for Approval of Outside Activity, to accept compensation for the lecture.
- c. An employee who is seeking non-government employment, or who is negotiating for non-government employment, should disqualify him/herself from any matters involving the outside entity unless the entity has absolutely no connections to the NIH, or the employee must obtain a waiver.
- d. Once it has been determined that no conflict exists (the employee is disqualified from official involvement with the potential employer), the employee may accept travel expenses and other reasonable expenses incident to non-government employment discussions, even from an entity that constitutes a prohibited source. (See Section 2635.602(b) of the OGE Standards of Ethical Conduct.) However, since a job search is a personal activity, the payment-in-kind (HHS Form-348) may not be used to fund the travel or obtain reimbursement.

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3. DISQUALIFICATION

The requirement for disqualification begins with the initial employment discussion (i.e, response to a resume) and ends when the discussions concerning possible employment terminate, for example, when either the employee or potential employer indicates that the process is terminated.

Disqualification involves the following guidelines:

- a. Disqualification is accomplished by not participating in a particular matter.
- b. The person responsible for the employee's assignment should be notified of the disqualification.
- c. Notice of disqualification (recusal) must be in writing and must identify an official above the employee's position to handle any matter dealing with the outside organization.

4. WAIVER

- a. Where an employee is engaged in discussions that constitute employment negotiations for purposes of 18 U.S.C. Section 208, the employee may participate in a particular matter that has a direct and predictable effect on the financial interests of a prospective employer only after receiving a written waiver from the official responsible for the employee's appointment. See Appendix 1 for an example of a waiver.

Example: Jane Doe is working on a CRADA with Upjohn. Jane Doe wishes to negotiate for employment with Upjohn. Jane Doe's Institute Director may, because of the importance of the CRADA to the Government and the standard for granting a waiver is met, give her a written waiver allowing her to negotiate with Upjohn while at the same time continuing to work on the CRADA with Upjohn.

- b. If a determination is made that a substantial conflict would arise if the employee was permitted to engage in employment negotiations while continuing to be involved in the official matter, the agency may allow the employee to take annual leave or leave without pay while seeking employment, or may take other appropriate administrative action.
- c. A sample waiver request is shown in Appendix 1.

OUTSIDE WORK AND RELATED ACTIVITIES WITH OUTSIDE ORGANIZATIONS

SAMPLE RECUSAL

[Date]

TO: Deputy Ethics Counselor
ICD

FROM: [Employee's name]

SUBJECT: Recusal -- Outside Activity with [name of outside organization]

This is to notify you that I have an approved ongoing Outside Activity with

[Name of the Outside Organization]

I have been advised that an Outside Activity may present an actual or appearance of a conflict of interest; therefore, I must disqualify/recuse myself from any official duty activities that involve the above organization. I understand that I may not participate personally or substantially as a Government employee in any matters regarding the above organization. Furthermore, I understand that under the Department of Health and Human Services' guidelines, it would be appropriate for any matters specifically involving the above named organization to be referred to my Supervisor without consulting me or informing me that such matters are pending. This action is taken with the concurrence of my Division Director, as indicated below.

I understand that this recusal will remain in effect until I inform you in writing that the Outside Activity has terminated, plus a 1-year "cooling off" period.

Employee

RECOMMEND:

Division Director

Date

APPROVE:

Deputy Ethics Counselor, ICD

Date

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INFORMATION on ACTIVITIES with OUTSIDE ORGANIZATIONS

Official Duty		Features of Outside Work and Official Duty Activities	Outside	
Yes	No		Yes	No
X		Work <u>related to</u> , or an extension of, employee's <u>official duties</u> .		X
X		Involves use of employee's <u>current and/or unpublished work</u> . Any project or undertaking performed within the last 12 months.		X
X		Involves employee's <u>previous</u> work performed prior to the last 12 months and using publicly disclosed information.	X	
X		Involves employee's general scientific or professional expertise or the policies of the outside organization.	X	
X		Employee <u>may have official business dealings</u> with an outside organization.		X
	X	Employee <u>may receive compensation</u> for performing the activity.	X	
	X	Employee may participate in the <u>business affairs</u> of the outside organization, including personnel actions, financial management or fund-raising activities.	X	
X		Employee performs <u>work on Government time</u> .		X
X		Employee <u>uses Government resources</u> (equipment, supplies, or staff).		X
X		Employee <u>uses Government space</u> and meeting rooms.		X
X		Employee uses official title to promote attendance at events.		X
Criteria That Apply to Both Outside Work and Official Duty Activities				
An employee may not represent an outside organization or serve as an expert witness before any agency of the Government, legislative body, court, or state or local entity in which NIH or HHS has a direct and substantial interest, unless authorized by the agency.				
The employee's activities may not constitute or present a real or apparent conflict of interest. The employee may not engage in any activity with an outside organization if the performance of the employee's official duties could affect his/her personal or imputed financial interests and those of his/her spouse and minor children. The employee must also avoid any situation or activity that gives rise to an apparent conflict of interest. This can occur when an employee is involved in a particular matter involving outside parties and the circumstances are such that a reasonable person with knowledge of the relevant facts would question the employee's impartiality.				

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Continued ...

Criteria That Apply to Both Outside Work and Official Duty Activities (Cont.)

The employee may receive payment for actual travel and other expenses. For an employee performing an official duty activity, the outside organization may reimburse the government for travel and other expenses related to the activity. An employee offered reimbursement must follow the applicable rules governing reimbursements from non-Federal sources, e.g., HHS Form 348 (Request and Approval for Acceptance of Payment of Travel Expenses from a Non-Federal Source) for an official duty activity. For an employee performing an outside activity, the outside organization may make a direct payment to the employee for travel and related expenses. The Government will not be involved in this type of transaction.

NIH only has an interest in activities that require the employee to use his/her professional qualifications readily identified with NIH employment. An employee may decide to moonlight using skills that are not professional in nature and are not related to his/her NIH duties, such as working in a performing arts company, teaching aerobics, working in a retail outlet or taking up furniture refinishing as a side occupation. An employee may engage in these types of activities without requesting approval.

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DETAILED INFORMATION ON WRITING, EDITING AND CONSULTING

The following is intended to provide more detailed information to determine which writing, editing and consulting activities can be performed as outside work and which should be performed as official duties.

1. **Writing and Editing Activities:** Writing or editing of a textbook, a book for the lay reader (i.e., a nontechnical medical guide or manual), or book chapter is most often performed as an outside activity. However, some writing and editing activities may be performed as an official duty subject to the following guidelines:
 - a. An employee may write a book as an official duty activity when describing or reviewing research results obtained under an official duty activity, e.g., from symposium proceedings. While a book may deal in part with the employee's official responsibilities, by nature it is generally much broader in scope and includes information in addition to the employee's official duties.
 - b. An employee may also edit a book and write or edit a chapter as an official duty activity when the topic is directly related to his or her official Government responsibilities. Edited or written material must include the following disclaimer: "Official contribution of the National Institutes of Health; not subject to copyright in the United States."
 - c. An employee represents the Government when performing the activity in an official duty capacity. A publisher may not copyright books and/or chapters written or edited by a Government employee in his or her official duty capacity, nor may an employee accept any money from the publisher or other outside organization for writing or editing performed as an official duty activity.
 - d. Except for reimbursement of actual expenses incurred, an employee may not accept compensation or remuneration (including royalties) for his or her participation in a writing or editing activity done as official duty, or use such funds in support of the official duty activity. Employees offered expense reimbursements must follow the applicable rules governing reimbursements from non-Federal sources, e.g., HHS Form 348 (Request and Approval for Acceptance of Payment of Travel Expenses From A Non-Federal Source).
 - e. Membership on an editorial board which reviews manuscripts and makes recommendations to another decision-maker may sometimes be done as official duty, depending on closeness to official duty responsibilities and ICD mission. If the board sets policy or makes the final decision for which papers get published, the employee's obligation is to the journal/publisher and this activity must be done as an outside activity.

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2. Professional and Consultative Services with Outside Organizations:

- a. Consultation with universities and private organizations to render scientific advice (e.g., on facilities, new products or scientific research) is generally permissible as an outside activity.
- b. Both NIH employees and approving officials should recognize that consulting for industry raises special concerns. "Industry" in this case means a for-profit firm or not for-profit organization which seeks to develop and/or market, directly or indirectly, a technique, process or product.
- c. While engaged in consulting with a particular company, the possibility exists that a situation could arise where an employee could be tempted to alter the direction of official research activities in order to benefit that outside company. In addition, the more time spent in an outside consulting activity, and the more the compensation received, the greater the potential for conflict of interest or adverse effect on the employee's official NIH responsibilities. Therefore, it is critical that consulting activities conform to all basic requirements governing outside activities in general and be carefully reviewed for appropriateness and lack of overlap with official duties.
- d. Consultation with a law firm is a permissible outside activity. However, NIH employees are prohibited from engaging in any activity that may be inappropriate because of the potential for embarrassment to the NIH, DHHS, or the Federal Government. For example, if an issue is highly controversial, or the general public may attribute an employee's private views to the NIH, the activity must be avoided. Decisions as to whether an activity should be avoided because it is controversial can be made by any official in the approval chain of authority. Since law firm consulting may eventually result in expert testimony, employees should be aware of the restrictions on their service as an expert witness (see section e. below).
- e. An employee cannot consult on a legal matter if the Federal Government is a party or has a substantial interest.
- f. No outside activity will be approved if there is a financial and/or business association between the employee's official duties and either the law firm or the parties involved in a litigation.

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 - b. An employee may also edit a book and write or edit a chapter as an official duty activity when the topic is directly related to his or her official Government responsibilities. Edited or written material must include the following disclaimer: "Official contribution of the National Institutes of Health; not subject to copyright in the United States."
 - c. An employee represents the Government when performing the activity in an official duty capacity. A publisher may not copyright books and/or chapters written or edited by a Government employee in his or her official duty capacity, nor may an employee accept any money from the publisher or other outside organization for writing or editing performed as an official duty activity.
 - d. Except for reimbursement of actual expenses incurred, an employee may not accept compensation or remuneration (including royalties) for his or her participation in a writing or editing activity done as official duty, or use such funds in support of the official duty activity. Employees offered expense reimbursements must follow the applicable rules governing reimbursements from non-Federal sources, e.g., HHS Form 348 (Request and Approval for Acceptance of Payment of Travel Expenses From A Non-Federal Source).
 - e. Membership on an editorial board which reviews manuscripts and makes recommendations to another decision-maker may sometimes be done as official duty, depending on closeness to official duty responsibilities and ICD mission. If the board sets policy or makes the final decision for which papers get published, the employee's obligation is to the journal/publisher and this activity must be done as an outside activity.

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- c. While engaged in consulting with a particular company, the possibility exists that a situation could arise where an employee could be tempted to alter the direction of official research activities in order to benefit that outside company. In addition, the more time spent in an outside consulting activity, and the more the compensation received, the greater the potential for conflict of interest or adverse effect on the employee's official NIH responsibilities. Therefore, it is critical that consulting activities conform to all basic requirements governing outside activities in general and be carefully reviewed for appropriateness and lack of overlap with official duties.
- d. Consultation with a law firm is a permissible outside activity. However, NIH employees are prohibited from engaging in any activity that may be inappropriate because of the potential for embarrassment to the NIH, DHHS, or the Federal Government. For example, if an issue is highly controversial, or the general public may attribute an employee's private views to the NIH, the activity must be avoided. Decisions as to whether an activity should be avoided because it is controversial can be made by any official in the approval chain of authority. Since law firm consulting may eventually result in expert testimony, employees should be aware of the restrictions on their service as an expert witness (see section e. below).
- e. An employee cannot consult on a legal matter if the Federal Government is a party or has a substantial interest.
- f. No outside activity will be approved if there is a financial and/or business association between the employee's official duties and either the law firm or the parties involved in a litigation.

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EXAMPLES OF OUTSIDE WORK AND OFFICIAL DUTY ACTIVITIES

The following examples are intended to present situations which NIH employees may encounter and explain how and why these activities are performed either as outside work or official duty activities. These examples are representative only and are not intended to replace the advice provided by ICD Deputy Ethics Counselors and/or Ethics Coordinators. Any questions concerning whether activities should be performed as outside work or official duty activities should be directed to the appropriate ICD officials.

1. Writing a textbook

A GS-14 scientist at the NIH, whose principal area of Government research is the molecular basis of the development of cancer, could not write a textbook as a compensated or uncompensated outside activity if it focuses on her specific Government research data. However, the scientist could receive compensation for writing or editing a general textbook on the treatment of all cancers, both surgically and medically, conveying scientific knowledge gleaned from the scientific community as a whole. The book might include a chapter, among other chapters, which discusses the molecular basis of cancer development which might include published research conducted more than 12 months ago. In addition, the book could contain brief discussions of recent developments in cancer, even though some of these developments are derived from NIH research, as long as this information is already available to the public.

2. Intramural employees involved in editing for a professional journal

A research scientist has been asked to edit material for a professional journal. The scientist asks the laboratory secretary to perform work related to the journal editing. This raises the question of whether the secretary is performing these duties as part of her officially assigned work or whether she is performing this work as an outside activity for which she can be paid.

If the scientist is performing these editorial functions as part of his official duties, then he may use Government time, equipment and the services of other employees. Therefore, any clerical or technical work associated with the scientist's editing activities can be performed by the laboratory secretary as part of her official duties. The secretary can perform the work related to the editing during normal business hours and she will receive her usual salary for performing these and other official duties. Since the secretary is performing these duties as part of the official work of the laboratory, she may also perform this work outside of normal business hours if she is authorized overtime to do so by the chief of the laboratory. However, under no circumstances can the secretary or the scientist engage in any outside work with the journal because they are already working with the journal as part of their official duties.

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The situation changes if the scientist is performing editorial functions as an outside activity. Outside activities are considered to be personal and not official business. If the journal editing is being performed as an outside activity, the scientist may not use Government time, equipment or the services of other employees. In this case, the secretary may not perform any clerical or technical work associated with the editing during normal work hours because the editing is not part of the official work of the laboratory. Furthermore, the scientist could not refer his secretary to the journal to be hired to perform the associated clerical work because the hiring of the secretary would be a direct result of her Government position. The only reason the secretary would be offered the position is because of her association with the scientist who is working with the journal as an outside activity. The Standards of Ethical Conduct prohibit a Government employee from using their Government position for either their own or the private gain of others.

3. Consulting on a professional area of personal expertise involving an incidental presentation

A Research Biologist, serving as a senior intramural investigator in the Parasite Growth and Differentiation Section of the Laboratory of Parasitic Diseases, is asked to consult with the faculty and graduate students at a University in the Midwest for a fee of \$2,000. This activity will transpire during one and one half days at the University. The first full day and all but 30 minutes of the four hours on the second day will be devoted to listening to presentations by the chairpersons of the various departments of research at the University, as well as personal one-on-one discussions with graduate students, to whom he provides an assessment/evaluation of their research projects.

During 30 minutes of the second day, the employee makes a presentation entitled, "The Importance of Parasitology in Biomedical Research." The content of this presentation does not specifically focus on his NIH responsibilities, which are primarily involved with the growth and differentiation of parasites. Rather, this presentation is generic--addressing the range of causes and effects that result from animal parasites invading the human body.

While it does contain some official information, the presentation at the University does not create a conflict of interest or appearance of a conflict because the information has been published. The university does not have, nor is it in the process of negotiating a CRADA or other collaborative research agreement with the employee, nor has it received, nor is it likely to receive, a contract or other funding from the part of the intramural program in which the employee works. He is undertaking this activity in a personal capacity and is not performing it as an official duty. The activity will be performed while on approved annual leave or leave without pay, and the outside work request, supplemental information sheet, and position description have been submitted at least three weeks in advance of the proposed activity.

4. Consulting in a review and evaluation context

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An SES level Chief of the Laboratory of Immunogenetics, who has a Ph.D. in Chemistry, is asked to consult with the Virginia Mason University Research Center about immunologic research for a fee of \$3,000 and travel expenses.

The employee, in her personal capacity, will serve as a member of a Visiting Committee, which will listen to scientific presentations by the chairpersons of the various research departments of the center and their junior staff at a research symposium. The employee is also expected to serve as an ad hoc reviewer and evaluator, providing feedback which will help to maintain the quality and research focus of the center's scientific program.

This activity will be performed as an outside activity rather than official duty activity. The activity is not in conflict with her official duties because she works in the specific field of immunogenetics and the activity involves reviewing basic immunologic research mostly conducted by junior staff. The employee will perform this consulting work while on approved annual leave or leave without pay, and the University is not a source which would create a conflict of interest or appearance of a conflict. This activity does not involve the use of current or unpublished official information.

5. Consulting for a law firm

A GS-15 scientist is asked to serve as a paid consultant for a Florida law firm representing the family of a individual who died of an aspergillus pneumonia, and who may have had chronic granulomatous disease of childhood. The consulting activities will consist of reviewing medical and other legal records; advising lawyers of certain medical facts relating to the case; providing personal opinions and perspectives relating to the care and treatment of the deceased; and potentially testifying in a state court as an expert witness should the case come to trial. The employee will receive consulting fees and will perform all activities after normal working hours at the employee's private residence or, while on approved annual leave or leave without pay, at the law firm's offices or in court.

Neither the deceased nor the family of the deceased have ever had any contact or interaction with either the employee or the National Institutes of Health, and the employee had no knowledge of the participants, or this particular case, prior to being contacted by the law firm. Since the clients are not a company or public concern, but rather private individuals, the issue of the employee owning stock or otherwise holding a financial interest in this case is not applicable.

Because there is no conflict of interest, infringement on the employee's ability to perform his official duties or issues that conflict with the position or policies of NIH, this activity may be performed as outside work.

6. Consulting in a group situation in the format of a round table discussion

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A medical officer oversees an epidemiological study that follows the habits and cardiovascular health of the people of a town over several generations to see how and why they die. This physician has been asked to consult with a company on the area of silent ischemia and the treatment and prevention of unrecognized myocardial infarction. This subject area is related to his general expertise and educational training. Each consultant reviews several research studies relating to the consultant's area of expertise and provides advice about their validity, applicability and limitations in a round table discussion.

Each scientist is assigned a time during which the other scientists and representatives of the marketing company will ask questions concerning that scientist's advice and impressions of the data. As a result of the advice, the marketing company will develop a report of recommendations to a specific pharmaceutical company, covering strategies for research and marketing of pharmaceutical products. This is an acceptable outside work activity because it is sufficiently separate from the employee's official duties. The discussion or even informal presentation that takes place during the activity is merely one part of the whole activity of an expert providing professional or technical advice.

7. Extramural employees engaged in consulting

A Health Scientist Administrator at the NIH is responsible for the administration of grants to universities in the area of cancer research. This employee is asked by a university to consult on trends in cancer treatments. The consulting would utilize the employee's general expertise in cancer research and treatments and would not utilize data from grants the employee administers. Since the university in this case does not have any grants that are in the employee's research portfolio, the employee would be able to undertake an outside activity with this university. However, should this university subsequently be awarded a grant that is assigned to the employee's portfolio, the employee would have to terminate his outside work activity with the university or disqualify himself from all matters in which that university might have an interest. If the employee's disqualification is approved, the management of this grant would have to be assigned to another Health Scientist Administrator of higher rank.

Another HSA administers grants to entities involved in AIDS research. The employee may engage in an outside activity as a Board member of a non-federal entity engaged in work on AIDS, so long as the employee has no official duties with that non-Federal entity. If the employee wants to participate as a Board member as an official duty, he would have to obtain a waiver to so participate (see Appendix 1, Sample 2). Or, the employee could serve as a Federal liaison to the Board of Directors of the non-Federal entity. He may engage in this activity, even if members of the non-federal entity may seek grants from his program so long as he is not involved in the seeking or review of the grants, unless his supervisor determines that the appearance of a conflict of interest is too substantial.

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A Health Scientist Administrator just assumed responsibility for a grant portfolio which includes grants with a university with whom the employee held a paid consulting arrangement until one month ago. This would create the appearance of a conflict of interest for which a waiver would be needed for the employee to continue to retain responsibility for the administration of this grant.

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OUTSIDE WORK, FINANCIAL INTEREST AND RELATED ACTIVITIES

INVITATIONS to WIDELY ATTENDED GATHERINGS

Definitions	
<p><u>Widely Attended Gatherings</u> - Meetings, conferences or other outside event attended by a large number of people from throughout an industry or profession, or if those in attendance represent a range of persons interested in the topic of the meeting, conference or event.</p>	
<p><u>Free Admission</u> - Includes all or part of any entry fee, food, refreshments, entertainment, instructions and materials provided to all attendees. It does not include travel expenses, lodgings, entertainment collateral to the event, or meals other than those taken in a group setting with all other attendees.</p>	
<p><u>Accompanying Guest</u> - If others in attendance will generally be accompanied by spouses or guests, or spouses and guests are specifically invited, the agency may authorize an employee to accept a sponsor's invitation of free attendance. The authorization for attendance of spouses or guest should be in writing.</p>	
<p>An employee may receive admission or an invitation to attend outside events free of charge, and may accept an offer subject to the following conditions:</p>	
Attendance	Conditions
Employee is a participant.	<p>Supervisory approval is required. Otherwise there are no limitations.</p> <p>An employee participating in an event as a speaker or panel member or leader to present information on behalf of the agency is considered to be performing her/his official duties. Attendance on the day of the presentation is free and is not considered a gift to the employee or the agency. The employee is not charged leave for the day.</p>
Employee attends on official time.	<p>Supervisory approval is required. Supervisors must determine that attendance at the event is in the interests of the agency.</p> <p>An offer of free attendance is considered a <u>gift to the agency</u> and not a gift to the employee when the employee attends on official time. The Standards of Ethical Conduct only apply when a gift is given to an employee.</p> <p>Any reimbursement for travel expenses should be pursued through the HHS-348 process.</p>

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Attendance	Conditions
Employee attends on own time or administrative leave.	<p>An offer is considered a <u>gift to the employee</u> if s/he plans to attend the event on her/his own time or while on administrative leave. The Standards of Ethical Conduct contain restrictions on gifts to employees, including the requirement that an employee must always obtain <u>oral permission from their ICD Deputy Ethics Counselor</u> before an offer can be accepted.</p> <p>The ICD Deputy Ethics Counselor must determine that the attendance of the employee is in the interests of the agency because it will further agency programs or operations.</p>
Employee attends an event sponsored by a prohibited source (i.e., a person or organization with interests that may be substantially affected by the performance or non-performance of the employee's official duties).	The employee must obtain <u>written permission from his/her ICD Deputy Ethics Counselor</u> that the employee's participation in the event outweighs concerns that acceptance of the gift may, or may appear to, improperly influence the employee.
More than one employee attends an event sponsored by a prohibited source	Several employees may attend the event if their <u>ICD Deputy Ethics Counselor</u> issues a blanket written determination to cover all invited employees.
Source of Invitation	Conditions
Event Sponsor	Large numbers of individuals with diversity of viewpoints attending the meeting, and no cap on the value of the gift of free attendance. Need agency determination that attendance is in the interest of the agency.
Other than Event Sponsor	The value of the gift, including any support for a guest, may not exceed \$250. At least 100 people must attend the event. Need agency determination that attendance is in the interest of the agency.
<p>Reporting Requirements - Employees must report, on their financial disclosure form, the gift of free attendance at widely attended gatherings if they attend on their own time and the offer of free attendance (e.g., registration, waiver of fees, etc.) is \$250 or more.</p>	

OUTSIDE WORK AND RELATED ACTIVITIES WITH OUTSIDE ORGANIZATIONS

GUIDANCE on the ACCEPTANCE of AWARDS

NIH employees make numerous outstanding contributions to the biomedical sciences. These contributions are frequently recognized by outside organizations in the form of awards. Employees may accept these awards subject to the following guidelines.

1. **Approval by a Deputy Ethics Counselor** - All awards from outside organizations must be approved in advance by a Deputy Ethics Counselor. In reviewing a request for approval to accept an award, the Deputy Ethics Counselor should consider the following points:
 - a. An award from an outside organization may be accepted for work performed at the NIH, and an employee may accept any money associated with the award.
 - b. An award may be accepted from most sources including those designated as prohibited sources, unless the source is an organization that has interests which may be substantially affected by the performance or nonperformance of the employee's official duties.

Example 1: An intramural employee works in a laboratory that has a CRADA and a contract with Bristol Myers. The employee, however, has no personal involvement or responsibility for the award or administration of either of these mechanisms. In this situation, the employee may accept an award from Bristol Myers because Bristol Myers is not an organization with interests that would be substantially affected by the performance or nonperformance of the employee's duties.

Example 2: An extramural Health Scientist Administrator (HSA) could receive an award from Johns Hopkins University as long as the HSA does not currently administer grants/contracts from Johns Hopkins. (Should an application from Johns Hopkins be received within one year from award receipt, the HSA should disqualify her/himself from handling the grant on the basis of the appearance of a conflict of interest.)

- c. An award may not be accepted if it is presented by an association or an organization, the majority of whose members would be substantially affected by the performance or non-performance of the employee's duties.

Example 3: An NIH scientist is to be given an award by a national voluntary or professional association. Even though most of the members of the organization either are or potentially are grantees of the employee's ICD, the scientist is not in a position to perform duties that will directly affect the members of the board. In addition, the grant applications of board members would be submitted by their

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- employing institution; they would not submit grant applications as members of the organization.
- d. A cash award, or one with a market value of more than \$200, requires a written determination by a Deputy Ethics Counselor that the award is made as part of an established program of recognition. Specifically, the determination must verify that:
- 1) The award has been made on a regular basis or, in the case of a newly created award program, is funded in such a way that continuation is ensured.
 - 2) The selection of the award recipient(s) is also made based on written standards or by an established selection committee.
- e. A non-cash award that has a market value of less than \$200 may be accepted if the award is a bona fide award or incident to a bona fide award that is given for meritorious public service or achievement, provided that the employee cannot substantially affect the interest of the organization or its members. A written determination that the award is made as part of an established program of recognition is not required in this instance.
2. **Official Duty Activity** - Acceptance of an award need not be approved as an outside activity. The employee should accept the award as part of his or her official duties or in his/her personal capacity while on approved annual leave.
 3. **Disqualification** - If the Deputy Ethics Counselor decides the acceptance of an award will result in the appearance of a conflict of interest, the employee will be asked to disqualify him/herself from all matters involving the awarding institution. If disqualification is deemed necessary, the employee will be excused from involvement in all matters associated with the awarding institution for up to one year from the date the award was received.
 4. **Documentation** - The following form should be used to document the approval of an award to an NIH employee by an outside organization. Since there is no central supply, this form should be reproduced locally.

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Approval of an Award from an Outside Organization

Name of Employee: _____

Name of Awarding Organization: _____

Name of Award: _____

Amount of Award _____

Date of Request: _____

Award Receipt Date: _____

1. Is this award being offered by an association or organization that has interests that may be substantially affected by the performance or nonperformance of the employee's official duties?
 No (Go to question 2.)
 Yes (The award may not be approved.)

2. Is this award being offered by an association or organization, the majority of whose members have interests that may be substantially affected by the performance or nonperformance of the employee's official duties?
 No (Go to question 3.)
 Yes (The award may not be approved.)

3. Is this award worth \$200 or less (either in cash or market value of the award).
 No (Go to question 4.)
 Yes (May be approved without written determination.)

4. Is this a cash award (or investment interest such as stock) or does it have a market value of more than \$200. (Market value includes the value of any tangible item, such as a crystal bowl, as well as the offer to pay travel expenses, meals, or a reception.)
 Yes
 No

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If the answer to #4 is yes, the award may only be approved upon a written determination by a Deputy Ethics Counselor that both of the following conditions are met:

- a. The award has been made on a regular basis:
 Yes
 No

- b. The award recipients are chosen based on written guidelines or by a selection committee.
 Yes
 No

This form constitutes my written determination that:

The acceptance of this award **is not** an appropriate official duty activity.

The acceptance of this award **is** an appropriate official duty activity.

and: The award **is not approved**.

The award is either not a cash award, or is an award that has a market value of less than \$200, and **is approved**.

The award is a cash award or has a market value of more than \$200, and **is approved**.

Deputy Ethics Official

Date

Period of Disqualification _____

Employee's Signature

Date

Note: All awards with a value over \$250 must be reported on the employee's next annual financial disclosure report.

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GUIDELINES on the ACCEPTANCE of HONORARY DEGREES

NIH employees make numerous outstanding contributions to the biomedical sciences. Contributions such as these are often of such merit that these scientists are honored by colleges and universities through the awarding of honorary degrees. The following guidelines apply to the acceptance of honorary degrees.

1. **Approval by a Deputy Ethics Counselor** - An employee may accept an honorary degree from an institution of higher education based on a written determination by a Deputy Ethics Counselor that the timing of the awarding of the degree will not cause a reasonable person to question the employee's impartiality in any matter affecting the institution. For example, the Deputy Ethics Counselor should verify whether there are any pending lawsuits, investigations, grant or contract applications or disputes, or other similar matters, involving the institution conferring the degree or the employee to whom the degree is offered. If such pending matters exist, a determination will have to be made, based upon the circumstances, as to whether the pending matter is such that the employee can accept the honorary degree.
2. **Disqualification** - To avoid any appearance of a conflict of interest, an employee must be disqualified from all matters involving the institution awarding the degree from the date that the approval is given to receive the degree through one year after the date the honorary degree is conferred.
3. **Official Duty Activity** - It is recommended that the employee accept an honorary degree as an official duty activity.
4. **Documentation** - The following form should be used to capture the information needed for an approval of an honorary degree by an NIH employee. Since there is no central supply of this form, it should be reproduced locally.

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APPROVAL OF ACCEPTANCE OF HONORARY DEGREE

Name of Employee: _____

Awarding Institution: _____

Date of Request: _____ Date Degree Will Be Conferred: _____

Period of Disqualification: _____

1. Are there matters pending, (e.g. lawsuits, investigations, disputes) involving the institution offering the degree that would mitigate against approval of receipt of the honorary degree?
Yes (Please describe the matters pending.) No

2. Will the timing of the award cause a reasonable person to question the employee's integrity in a matter affecting the institution?
Yes (Please describe the circumstances.) No

Receipt of the honorary degree is approved based upon my determination that the timing of the award of this degree would not cause a reasonable person to question the employee's integrity in a matter affecting the institution.

Receipt of the honorary degree is disapproved. (See explanation that follows.)

Deputy Ethics Counselor Date

3. Does the employee agree to one year's disqualification from all matters involving the institution?
Yes (All such matters must be referred to the employee's supervisor.)
No (If no, receipt of the honorary degree is disapproved.)

Employee Signature Date

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OUTSIDE WORK AND RELATED ACTIVITIES WITH OUTSIDE ORGANIZATIONS

POST-EMPLOYMENT RESTRICTIONS

There are a number of restrictions imposed on Federal employees once they leave the Government. These restrictions are contained in 18 U.S.C. Section 207 (the Government-wide post-employment statute) and 41 U.S.C. Section 423(f) (applicable to procurement officials). This section describes the employees covered by these restrictions, and the general and specific rules and restrictions.

1. **Covered Employees** - Some post-employment restrictions apply to all Federal employees, regardless of grade or position. The rest apply only to procurement officials, trade negotiators, or senior employees. The applicability of these restrictions to each category of employees is noted below.

Post-employment restriction rules do not apply to Guest Researchers, Special Volunteers, National Research Council Research Associates, nor to others who have not been appointed as regular employees or Special Government Employees.

2. **General Rules**

- a. NIH employees may accept generally any employment after leaving Government service, with any private or public employer. (If you worked on a contract over \$10 million, additional prohibitions may apply. Consult your Deputy Ethics Counselor.)
- b. Former NIH employees may engage in any work for their new employers except for the specific restrictions outlined below.

3. **Specific Restrictions** - 18 U.S.C. Section 207 prohibits former NIH employees from engaging in certain activities, usually referred to as representational activities, on behalf of persons or entities other than the United States, whether or not done for compensation. Representational activities are activities on behalf of an outside entity, intended to influence a Government agency, and are summarized below. Employees should consult with ICD Deputy Ethics Counselors or Ethics Coordinators about specific post employment questions. There are several restrictions set forth in 18 U.S.C. Section 207 that apply to former NIH and other Federal Government employees:

- a. Lifetime bar on matters involving direct and personal participation. This is the primary post-employment restriction contained in 18 USC Section 207 and it applies to all employees. It is sometimes called the "lifetime bar" because a former Government employee is permanently restricted from representing an outside entity back to the Government, with the intent to influence the Government, on a particular matter involving specific parties (such as a contract, grant, approval, or other decision) in which the former employee was personally and substantially involved while a Government employee. This is generally known as the prohibition against "switching sides."

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Example 1: An NIH employee is serving as a project officer and working with Research-Tech, a research company, on a grant to develop a health reform proposal. After the project officer leaves NIH, she goes to work for Research-Tech. The former NIH employee is permitted to do technical work on the grant and discuss with NIH only technical, factual information regarding the grant. She may **not** argue for increased NIH funding of the grant, because that would be a communication to the Government with the intent to influence (representational).

- b. Two-year bar on matters under official responsibility. This restriction is almost the same as the one above, except that it only applies to managers and supervisors. Under this restriction, for two years after leaving the Government, a former employee may not represent any outside entity back to the Government, with the intent to influence, on a particular matter involving specific parties which was under the former employee's official responsibility in the last year of Government employment.

Example 2: After leaving an ICD, a former employee may apply as the principal investigator for a grant from his previous ICD, so long as the grant was not pending under his official responsibility while he was at the ICD. If, however, the former employee is asked to become co-principal investigator on a grant which had been pending under his official responsibility during his last year at the Institute (or one which he had reviewed at any time while he was a Government employee), he must be very careful that any communications he makes to the Institute are for the purpose of imparting only factual or scientific/technical information. As noted in the example above, the former employee must also strictly avoid making any statements that could be viewed as "representational."

The two-year bar refers to the lifetime of a particular matter. Once the matter has terminated, the prohibition ceases to exist. These restrictions only apply to communications made with the intent to influence NIH or other Government agencies on the particular matter. Communications of a purely factual, scientific or technical nature are not usually made with the intent to influence, and, as a result, would not be subject to these restrictions.

- c. One-year bar on trade and treaty negotiations. This restriction prohibits all former employees from knowingly representing, aiding or advising any other person concerning any ongoing trade or treaty negotiation in which they participated during their last year of Government service. Note that this bar prohibits behind-the-scenes aid or advice to anyone other than the United States in connection with the trade or treaty negotiations--not just representational activities as with the first two restrictions.
- d. Senior employees - The following two restrictions only apply to a "senior employee," that is, an employee defined as:

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- (1) A Presidential appointment subject to Senate confirmation who receives a rate of pay equivalent to levels II through V of Executive Schedule;
- (2) An employee whose rate of pay is equal to or greater than the rate of basic pay for level V of the Executive Schedule which would specifically include the following categories:
 - (a) SES employees at ES-5/6;
 - (b) Senior Level (ST & SL) employees paid at or above level V of the Executive Schedule;
- (3) Any Special Government Employee (SGE) paid at an hourly or daily rate that when annualized amounts to Executive level V or above, provided the SGE has served 60 days or more during the one-year period before that SGE's service as a senior employee terminates;
- (4) Any full or part-time employee paid at an annual salary equal to Executive level V or above (NIH employees that might be paid at or above this rate of pay include Visiting Scientists and members of the Senior Biomedical Research Service (SBRSS)); and
- (5) All commissioned officers of the uniformed services assigned to pay grade 0-7 or above.

The first restriction for senior employees is found in 18 U.S.C. 207(c), and is known as the one-year "cooling-off" period. This rule prohibits former senior employees from communicating or making an appearance before their former agency, with the intent to influence, for one year after leaving senior service. Also, this ban (unlike the permanent and two-year bans discussed above) is not limited to "particular matters involving specific parties." It covers general regulations, legislation and policy issues.

Example 3: Under this restriction, a former NIH Institute Director would be prohibited, for one year, from calling or writing to NIH to advocate adoption of tougher guidelines for promoting objectivity in research.

The second restriction for senior employees under 18 U.S.C. 207(f) is a one year bar that prohibits the former senior employee from knowingly aiding, advising or representing a foreign entity, with the intent to influence the official actions of **any** employee of the Government.

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- e. Senior Appointee Pledge - Executive Order 12834 was the first executive order signed by President Clinton. This Executive Order requires that all full-time, non-career Presidential, Vice Presidential, or agency head appointees (senior appointees) whose basic rate of pay is not less than the rate for Executive Level V, be subject to the additional restriction which effectively extends the one-year restrictions described above for "senior" employees to a five-year period. The Senior Appointee Pledge applies only to new political appointees and not to career SES or holdover appointees.
- f. 18 U.S.C Section 207 restricts former employees from **representing** vendors back to the Government on contracts or other actions on which they worked while they were Government employees, as outlined earlier. The 1997 amendments to the Procurement Integrity Act set dollar thresholds (\$10 million) for contracts, below which prohibitions remain the same, and above which prohibitions are more stringent. Employees who were involved in procurement matters and are leaving Government service should consult their Deputy Ethics Counselor prior to their departure to assure that they have the most current information concerning their future involvement in Government contracts.
- g. Five-year bar for employees taking buyouts. There is an additional restriction for employees who took advantage of the "buyout" or voluntary separation incentive payments offered by some organizations for leaving the Government under the Federal Workforce Restructuring Act.

Under these "buyout" provisions, Federal employees are prohibited for 5 years from entering into personal services contracts with the Government. There are exceptions, however, which allow the Government to contract with former employees for certain services as detailed below.

- 4. **Exceptions to the Prohibitions** - There are certain exceptions to Section 207, which if applicable, may provide relief from some of the restrictions in Section 207. Employees should be cautioned that these exceptions are complicated and must be applied carefully to any given factual situation. For information on these exceptions, questions should be directed to the Office of the General Counsel, Ethics Division. Generally, the exceptions include the following:
 - a. An exception is provided for most of the post-employment restrictions when the post-employment activities are performed:
 - (1) In carrying out official duties on behalf of the United States (does not apply to the "buyout" law); or,

In carrying out official duties as an elected official of a state or local Government (does not apply to the Procurement Integrity Rules).

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- (2) An exception is provided to all the restrictions of 18 U.S.C. 207 for former employees employed by a recognized Indian tribe when communicating on behalf of the tribe. This applies to all former employees, not just Indian Health Service employees. In order for this exception to apply, the former employee must provide written notification to the head of the department, agency, court, or commission with which he or she is dealing or appearing on behalf of the tribe of any personal and substantial involvement he or she may have had as an employee of the United States in connection with the matter involved [25 U.S.C. 450 (j)].
 - b. Another exception is provided to all the restrictions of 18 U.S.C. 207 for former employees when communicating on behalf of, or advising or aiding, an international organization in which the United States participates, such as NATO, the UN, or WHO, if the Secretary of State certifies in advance that such activity is in the interests of the United States.
 - c. Exception for Former Senior Employee - An exception is provided to former senior employees for the one-year "cooling-off" (and the five year senior appointee pledge period) when the communication or appearance is made in carrying out official duties as an employee of, and on behalf of:
 - (1) An agency or instrumentality of a State or local Government,
 - (2) An accredited degree-granting institution of higher education as defined in section 1201(a) of the Higher Education Act of 1965, or
 - (3) A hospital or medical research organization exempted and defined under section 501(c)(3) of the Internal Revenue Code of 1986.
5. **Public Financial Disclosure Reports (SF-278).** Those employees required to file Public Financial Disclosure Reports (SF-278) must report arrangements for future employment on Schedule C, Part II. Regardless of whether or not employment negotiations are successful, these employees must report any payment received from prospective employers for interview trips. In addition, all such employees are required, within thirty (30) days of leaving Federal service, to file a termination SF-278 report.

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PROCEDURES for REQUESTING APPROVAL of OUTSIDE ACTIVITIES

The NIH requires that each employee obtain advance approval for any outside activity which requires the use of professional qualifications readily identified with NIH employment. Activities subject to this requirement include:

1. Teaching, lecturing and giving speeches;
2. Providing professional and consultative services with outside organizations;
3. Conducting outside professional practice;
4. Serving as a member of a board or committee;
5. Writing, editing, and publishing;
6. Holding office in a professional organization; and,
7. Conducting other activities which specifically employ the general professional expertise related to the employee's NIH duties and responsibilities.

Preparation of Requests

All requests must be made by submitting Form HHS-520 (Request for Approval of Outside Activity) and supporting supplemental information to the employee's supervisor. Guidance on submitting requests and copies of all supplemental forms are included as Illustrations 1 through 5 of this Appendix.

Approving Officials

1. All requests for approval of outside activities for ICD Directors and ICD Deputy Ethics Counselors must be approved by the Deputy Director, NIH.
2. Requests from the staff of the Office of the Director, NIH, to engage in outside work activities must be approved by the OD Deputy Ethics Counselor.
3. All other requests for approval of compensated outside activities must be approved by the ICD Deputy Ethics Counselor.
4. Deputy Ethics Counselors may re-delegate approval authority for uncompensated activities to a level high enough to be consistent with good management of the authority. Activities for expenses only are considered uncompensated activities, except for teaching, speaking, and writing activities. In these cases, compensation also includes travel expenses, whether provided in-kind or reimbursed.
5. During long absences, a Deputy Ethics Counselor may designate another person at a high level in the ICD the authority to approve compensated outside activities.

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Required Documentation for the Submission of Outside Activity Requests

For each type of activity listed below, an X in the forms columns indicates whether that form is required to request approval for the particular activity listed. All forms are required for compensated activities, except as noted below. The unnumbered Supplemental Information form and a Position Description (PD) are optional for uncompensated activities, unless required by your ICD. Contact your Deputy Ethics Counselor or Ethics Coordinator for additional information.

Type of Activity	HHS-520	NIH-2657	Supplemental Form	Position/Billet Description
Teaching	X	X	X*	X*
Lecturing	X	X	X*	X*
Giving Speeches	X	X	X*	X*
Consulting	X	X	X*	X*
Consulting with Law Firms	X	X	X*	X*
Service on Boards	X	X	X*	X
Writing and Editing	X		X*	X*
Clinical Practice	X	X		

* Unless required by your ICD, the supplemental form is not required if the activity is uncompensated or is to be performed for expenses only, provided the nature of the activity is made sufficiently clear on the HHS-520.

It is recommended that a letter of invitation and/or agenda for an outside activity be added to the documentation presented for review.

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Instructions for Completing the HHS-520

Upper right hand corner - check appropriate box

- o Initial Request - first request to perform activity.
- o Revised Request - revises an initial request.
- o Renewal - to continue an activity past the period initially specified in 8a.

Block Number:

1. Name - Self explanatory.
2. Organizational Location - Provide name of ICD, Division, Branch, Laboratory.
3. Title of Position - Self explanatory (i.e., Visiting Scientist, Expert, Nurse, etc.).
4. Grade and Salary - Self explanatory (i.e., CO-5 \$70,000).
5. Identify the Person, Business or Organization for Whom Outside Services will be Performed - If the activity is a conference, lecture or teaching assignment, identify the organization responsible for the invitation and/or selection of topics. That organization may not necessarily be the one providing compensation (i.e., a pharmaceutical company provides funding to a university to set up a conference and allows the university to set the agenda and determine speakers). In this case, is the university the organization for whom services will be performed. However, where an invitation to speak at a conference is extended by the conference organizing committee, it can generally be assumed that the organizers are acting on behalf of the society or groups sponsoring the event.
6. Location Where Services will be Performed - Indicate City and State. If the employee lives in Bethesda, MD and intends to work at home, this should be annotated to include "Residence". This will avoid any misinterpretation that the work is being performed at NIH.
7. Nature of Activity
 - a. State whether the activity is:
 - i. teaching or lecturing,
 - ii. consultative services,
 - iii. clinical practice,
 - iv. membership on a board or committee,

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- v. writing or editing, or
 - vi. consulting for a law firm.
- b. Provide a full description of specific duties or services to be performed.
- c. If the request is to perform a writing/editing activity, include the title of the chapter, book or journal and the statement "The HHS requirements with regard to writing and editing done not as part of official duties will be observed." If you have any questions on this point, please refer to Appendix 7 of this manual.
- d. If the request involves the presentation of a lecture, be sure to include the title of the lecture and the statement "The information to be presented has been previously published or presented at public meetings at least one year ago or is available to the public."
- e. If the request involves the provision of consultative services, indicate the names of the individuals with whom you will be consulting and the topics to be discussed during the consultation. Also add the statement that "DHHS and NIH requirements regarding consulting will be observed."
- f. State whether you (or someone you supervise):
- i. have extramural program responsibilities;
 - ii. are a project officer;
 - iii. have direct business dealings, as a government employee, with the sponsoring organization; or,
 - iv. manage a portfolio that includes grants or contracts involving the organization.
- 8a. Period Covered - Include travel time.
- 8b. Estimated Total Time Devoted to Activity - estimate actual hours involved plus preparation time. Also include total hours for all approved activities for the current calendar year. Do not include hours spent traveling in this block.
- 8c. Will Work Be Performed Outside of Usual Working Hours - Show the amount of annual leave that will be taken for this activity. Note that Commissioned Officers may only take whole days of annual leave, not hours.
9. Do Your Official Duties Relate in any Way to the Proposed Activity? Answer yes or no. Provide details on the Supplemental Form, question #3.

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10. If providing Consultative or Professional Services, are Your Would-Be Associates Receiving or will They Seek, a Grant or Contract from HHS? Self explanatory. If yes, provide specific details on the Supplemental Form, question #4. (See Appendix 7)

11. Method or Basis of Compensation - Check the appropriate box. Note that expenses should be indicated separately from other compensation. Although the form asks for information on the amount of compensation that is to be received for the outside activity, **this information no longer has to be provided.**

Fee - Compensation from consulting, patient care, writing/editing, committee member, board membership, teaching, etc.

Royalty - Compensation for writing a book or a chapter for a book (can be shown as % of sales) and/or patented inventions or licensing of other intellectual property.

Honorarium - Compensation for a one time speech, article, or appearance.

Expenses - Compensation for travel, lodging, meals.

12. Will Compensation be Derived From a DHHS Grant or Contract? Note that Federal employees may not be compensated from HHS funds.

- 13./14./15. Self explanatory.

16. Additional Information Attached - Mark as appropriate. If additional information is provided, mark yes and include all documents related to the activity, other than the HHS-520. See Appendix 13, Illustration 1, for required documentation. Please attach the letter of invitation or request for services from your proposed employers.

17. Action Recommended - Be sure that Recommending Official has checked Approval/Disapproval block and has signed and dated request.

18. Action Taken - Show title of ICD Deputy Ethics Counselor.

Please note: If the request is from an ICD Director, the title of the approving official is Deputy Director, NIH.

OUTSIDE WORK AND RELATED ACTIVITIES WITH OUTSIDE ORGANIZATIONS

HHS-520, Request for Approval of Outside Activity

NOTE: This is a reduced copy. Contact your Ethics Coordinator for an actual form.

Prepared by:		Bldg./Room:		Phone:	
REQUEST FOR APPROVAL OF OUTSIDE ACTIVITY*					Initial Request
(Ref.: HHS Standards of Conduct Regulations)					Revised Request
					Renewed
1. Name: (Last, First, Initial)			2. Organizational location: (Operating Division, Bureau, Division)		
3. Title of position			4. Grade and salary (Federal)		
*5. Name, address and business of person or organization for whom outside services will be performed			6. Location where services will be performed		
7. Nature of activity (Indicate type of activity, e.g., teaching, consultative services, and give a full description of specific duties or services to be performed. Specify, when possible, the scheduled days of week and hours of day proposed activity will be performed.)					
8. Estimated time involved					
a. Period covered		b. Estimated total time devoted to activity <i>if on a continuing basis, give estimated time per year</i>			
From _____ To _____					
c. Will work be performed entirely outside usual working hours? <input type="checkbox"/> Yes <input type="checkbox"/> No If "NO," indicate estimated number of hours or days of absence from work					
9. Do your official duties relate in any way to the proposed activity? <input type="checkbox"/> No <input type="checkbox"/> Yes (Describe)					
*10. If providing consultative or professional services, are your would-be associates receiving or will they seek, a grant or contract from a federal agency? <input type="checkbox"/> No <input type="checkbox"/> Yes (Describe)					
11. Method or basis of compensation			12. Will compensation be derived from a HHS grant or contract?		
<input type="checkbox"/> Fee <input type="checkbox"/> Honorarium <input type="checkbox"/> Per Diem <input type="checkbox"/> Per Annum <input type="checkbox"/> Royalty <input type="checkbox"/> Expenses <input type="checkbox"/> Other (Specify)			<input type="checkbox"/> No <input type="checkbox"/> Yes (Describe)		
13. This request is made with full knowledge of department and operating division policy and procedures on outside activities. The statements I have made are true, complete and correct to the best of my knowledge and belief.					
14. Signature of employee		15. Date		16. Additional information attached	
				<input type="checkbox"/> Yes <input type="checkbox"/> No	
*17. Action recommended by reviewing official					
a. <input type="checkbox"/> Approval <input type="checkbox"/> Disapproval		b. Signature		c. Title	
				d. Date	
18. Action taken					
a. <input type="checkbox"/> Approval <input type="checkbox"/> Disapproval		b. Signature		c. Title	
				d. Date	
* See reverse of form HHS-520 (1/82)					

OUTSIDE WORK AND RELATED ACTIVITIES WITH OUTSIDE ORGANIZATIONS

HHS-520, Page 2

INSTRUCTIONS

- * Item 5 - Self-Employment: If applicable, indicate self-employment, the type of service (as medical, legal, etc.), whether alone or with partners, giving their names, and, if providing professional services to a large number of clients or patients, estimate the total number rather than listing them separately.
- * Item 10 - Federal Grants or Contracts Involved: Describe the Federal grants or contracts (type, granting or contracting department, etc.). Full details must be provided on any aspect of professional and consultative services which involves, directly or indirectly, the preparation of grant applications, contract proposals, program reports, and other material which are designed to become the subject of dealings between institutions and government units and the Federal Government.
- * Item 16 - Attachments: Be sure to sign copies of all attachments submitted.

* ITEM 17 - COMMENTS OF REVIEWING OFFICIAL

* ITEM 18 - REASON FOR DISAPPROVAL

OUTSIDE WORK AND RELATED ACTIVITIES WITH OUTSIDE ORGANIZATIONS

Supplemental Information to the HHS Form 520
(Unnumbered NIH Form)

Supplemental Information to the HHS Form 520

Employee Name:

Position Title:

Organization Location: (include ICD, Division, Laboratory, Branch, etc.)

1. Brief description of employee's official duties. In addition, attach a copy of the position description or billet.
2. Brief description of the outside activity.
3. Explain how the proposed outside activity is different from the scientific activities performed as part of your official duties.
4. A. For intramural employees, is the outside organization a recipient or potential recipient of any grants or contracts from your laboratory/ branch? Is the outside organization a recipient (or in the process of negotiating) any direct or indirect collaborative agreements or Cooperative Research and Development Agreements (CRADA) with your laboratory/branch? Is there any direct or indirect support of staff, guest researchers, or other individuals in your laboratory/branch?

OR

- B. For extramural employees, is the outside organization a recipient or potential recipient of any grants or contracts from NIH?
5. If consulting with a law firm, do you have any financial associations with the client (or potential beneficiary) in the matter for which you propose to consult?

OUTSIDE WORK AND RELATED ACTIVITIES WITH OUTSIDE ORGANIZATIONS

Unnumbered NIH Supplemental Form, Page 2

NIH Supplemental Form (Page 2 of 2)		
The following questions must be completed for outside activities with for-profit organizations. (If the answer to any question is YES, attach a separate sheet providing additional information on the item.)		
	YES	NO
6. Have you ever been denied approval for this outside activity before? _____		_____
7. Do you or any member of your family own stock, have stock options, or any other financial interest in the organization for which you propose to work?	_____	_____
8. As a part of your official responsibilities, have you made procurement or financial decisions, or are there any pending decisions that you will have to make, which will affect the business prospects of your proposed employer?	_____	_____
9. Have you worked, are you working, or do you anticipate working with a product of the company? If so, please describe this work on an attached sheet.	_____	_____
10. Are there any circumstances that you are aware of, associated with either the initiator of the request for outside activity or the prospective outside employer, which might create a real or apparent conflict of interest if this proposed activity is approved?	_____	_____

**Supplement to Form HHS-520,
"Request for Approval of Outside Activity"**

Instructions: Use this supplement with Form HHS-520 for all compensated activities except writing and editing or service on boards or committees.

Initiate Form HHS-520 far enough in advance of the activity so that it reaches the ICD Deputy Ethics Counselor in sufficient time for approval prior to the date of the activity. Standards of Ethical Conduct for Employees of the Executive Branch and NIH Manual Chapter 2300-735-4 contain the rules and regulations pertaining to outside activities.

Complete Part A. Complete Parts B,C,D and/or E when applicable. Submit this form with Form HHS-520.

Part A - General Information

Name (Last, first, middle initial)	Organization Location	Grade and Salary
Title of Position	Type of Activity	
Name of Outside Organization	<input type="checkbox"/> Teaching/Lecturing	<input type="checkbox"/> Consulting with Law Firm
	<input type="checkbox"/> Consulting	<input type="checkbox"/> Clinical/Private Practice

Part B - Complete only if you are Lecturing, Consulting, or Consulting with a Law Firm

Amount of compensation from the attached activity \$	Including this request, total compensation scheduled to be received this calendar year from all activities with this outside organization. \$	Including this request, total service time for all outside activities (except for writing and editing activities). Hours
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Part C - Employment Agreement for Consulting

This contract relates to consulting work proposed by an Outside Employer and the Employee, identified herein as the Consultant.

The following items are agreed to by both the Outside Employer and the Consultant:

- The proposed work will not interfere in any way with the Consultant's responsibilities at the NIH and will be performed only on non-duty time, annual leave, or leave without pay.
- The Consultant will not disclose to the Outside Employer any information derived from work at the NIH until it has been disclosed publicly, either in a written publication, or in an oral presentation at a lecture or meeting open to the public or publicly announced.
- Consultation will relate only to the general knowledge and expertise of the Consultant, and may be performed on an ongoing basis; however, all information concerning NIH research shall be provided on a non-exclusive basis. Any and all agreements for exclusive consultation are prohibited.
- The Outside Employer will have no proprietary interest in any work that the Consultant has done or will do at the NIH.

- Notwithstanding any other provision in the agreement, the Consultant shall not be restricted from reporting an invention made by the Consultant (whether alone or jointly) to the Department of Health and Human Services (HHS) as required by Federal regulations in 45 CFR Part 7,* nor shall anything in the Contract restrict or preclude the ability of HHS to ascertain its rights in such an invention.
- The Outside Employer will not refer to the Consultant or to an affiliation with NIH in anything distributed for publicity or product promotion.
- The number of days the Consultant will work for the Outside Employer during the period of this contract will be: _____ days during _____(year) and _____ days during _____(year).
- The method and amount of compensation of the Consultant's services and expenses will be as follows: the employee will receive a fee of \$ _____ per _____.
- This Consulting agreement shall become effective the date of NIH approval of the Consultant's participation in this Outside Activity.

* These regulations require the reporting of any invention made by a HHS employee that bears any relation to his/her official duties, or that was made in whole or in part during working hours, or with any contribution of Government facilities, equipment, material, funds, or information or of time or services of other Government employees on official duty.

Approval by Outside Employer: Signature of Designated Official	Date
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Typed Name of Designated Official	Position in Organization
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Phone No.	Address
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Part D--Employment Agreement for Testimony in Private Litigation and/or Legal Consultation with Company/Law Firm

In providing testimony in private litigation and/or consultation with the company or law firm shown in Part A, I agree to comply with the following guidelines in accordance with NIH Manual 2300-735-4:

1. No NIH information or data will be used that has not yet been published.
2. No present or former NIH patient names or records will be used.
3. If I am requested to review a case involving any present or

former NIH patient, I will disqualify myself.

4. Any opinion rendered will be my own personal opinion and not that of NIH or the Department.
5. The subject of the litigation is not controversial and is not likely to become controversial in the future, and
6. No activity will be approved when there is a financial and/or business association between the employee's official duties and either the company or law firm or the parties involved in the litigation.

Employee's Signature	Date
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Part E -- Employment Agreement for Outside Professional Practice

In providing outside professional practice with

I agree to comply with the following guidelines in accordance with NIH Manual 2300-735-4:

1. I will never knowingly establish a physician-patient relationship in outside professional practice with any current or recently discharged NIH patient.
2. If I have final responsibility for the admission of patients to the Clinical Center, I acknowledge that I may not receive a fee for service as a consultant to another physician where the condition of the patient would appear to make the patient eligible for Clinical Center admission in an area currently supervised by me.
3. I certify that I will comply with NIH regulations relating to Outside Work and Activities, as defined in Manual Issuance 2300-735-4.
4. I certify that patient support provided by me will not be done during my official NIH working hours and that I have made

arrangements with the organization named above for coverage for emergencies and activities with patients while I am on duty at NIH.

5. I certify that I will not have patient contact under this outside activity, including telephone calls, during my official NIH working hours. The organization named above is aware of this condition and has made other arrangements for patient contacts.
6. I certify that this activity will be conducted under the conditions that NIH patients will not be referred to the private practice of an NIH employee, nor from such practice to the NIH, and that patients will be informed in advance of this policy.
7. I certify that the outside activity is of such a nature that it will not interfere with my ability to perform fully my NIH duties. I further certify that the outside professional practice does not have, nor anticipate having, any financial dealing (e.g., contract, CRADA, or official duty) with my laboratory or branch.

Employee's Signature	Date
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I concur that to the best of my knowledge this activity represents no conflict of interest or conflict of commitment between the conduct of the outside professional practice and the interests of NIH.	Signature of ICD Deputy Ethics Counselor	Date
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